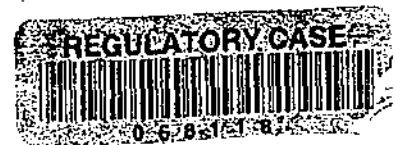


CANNED



072977-00002



Minutes of Meeting Held April 24, 2001

Company: ETI, H2O, Inc.
Route 14
Box 1517
Lake City, FL 32024

Products: Axen
EPA File Symbol 72977-E

Axenohl
EPA File Symbol 72977-R

Attendees: Company representatives: Andrew B. Arata, Mitch Cohen, and
Edwin A. Woolson and Henry Jacoby consultants.

EPA representatives: Nancy Whyte, Alex Traska, Martha Terry, and
Marshall Swindell

The meeting centered on the deficiencies noted in the last agency letter to the company for both products (an EPA letter dated 3/15 /01).

1. After significant discussion of the applications and the preliminary efficacy data on citric acid, it was determined that citric acid will be declared as an active ingredient. The preliminary data showed that citric acid did show from a 42% - 64% reduction of microorganisms in the percent reduction test conducted by the company (this data was submitted for informational purposes only, and was not officially reviewed by EPA, nor received a MRID number).

2. The company is using the Selective method of support and will submit a new "Certification With Respect to Citation of Data Form" listing both silver and citric acid as the active ingredients.

3. The company will submit a new data matrix for each product formulation, for technical silver and for technical citric acid. A registration standard has been issued for both silver and citric acid. Most of the data in both standards have been waived or satisfied by use of public literature data.

4. The company will submit a "Certificate of Analysis," and a Material Safety Data Sheet (if available) for the technical silver and citric acid.

5. The company has submitted five acceptable acute toxicity data on the Axenohl (0.24% silver, and 20% citric acid formula); however, no acute inhalation study or data waiver request has been submitted. The company will submit a waiver request for the inhalation data requirement after discussing the content of the waiver with AD's toxicologist. [consult with Wallace to see if the data on the Axenohl can be used for the Axen formula???]

6. The efficacy use dilution study (MRID# 45016906) will be placed into review ASAP. Nancy Whyte indicated that she would be will to conduct the review if the package is assigned to her. The data on Enterococcus which was previously reviewed and found to be unacceptable will not be used for these products.

7. The company will submit a new Confidential Statement of Formula form for each product declaring citric acid as an active ingredient.

8. The company will submit new labeling for each product. The new labeling will drop all virucidal claims; declare citric acid as an active ingredient; include appropriate First Aid instructions in accordance with PR Notice 2001-1; delete any reference to use of the product on textiles or other surfaces which are not environmental, hard and nonporous in nature.

9. The company will submit a letter designating Henry Jacoby as their new agent.

For any questions or inquiries, please contact Martha Terry at 703-308-6217 or Marshall Swindell at 703-308-6341.

DECISION PKG. NO. 340146
755664SUBM. DUE DATE 4/2/04SUBMISSION BAR CODE # 129322REVIEWER JKCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 72977-2 PM 33 ACTION CODE 332DESCRIPTOR Notification FQPA X NFQPA☐ CHILD RESISTANT PACKAGING: ☐ REQUIRED ☐ NOT REQUIREDREGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL ☐ RESTRICTED USE

DATE ON APPLICATION

3/2/04

EPA RECEIVE DATE

3/3/04

PM RECEIVE DATE

3/3/04

METHOD OF SUPPORT

☐ CITE-ALL ☐ SELECTIVE
☐ NOT SUBMITTED ☐ N/A

FORMULATORS EXEMPTION

☐ SUBMITTED ☐ NOT SUBMITTED
☐ N/A

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNEDCHEMISTRY ☐ ☐ ☐ ☐EFFICACY ☐ ☐ ☐ ☐ACUTE TOX. ☐ ☐ ☐ ☐RASSB TOX. ☐ ☐ ☐ ☐ENVIRON. PATE ☐ ☐ ☐ ☐FISH/WILDLIFE ☐ ☐ ☐ ☐OTHER: ☐ ☐ ☐ ☐

STATUS _____

RESPONSE CODE 17RESPONSE DATE MAR 30 2004 ✓

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 30 2004

Dolana Blount
ETI
1725 Gillespie Way
El Cahan, CA 92020

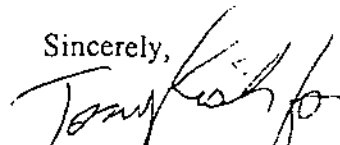
Subject: EPA Reg. No. 72977-2
Axen
Notification Dated 3/2/04

The notification referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to expand and clarify the current pre-cleaning statement, "Surfaces that are heavily soiled with organic matter must be pre-cleaned prior to using this product", to the following, "Prior to application, thoroughly clean all surfaces to be treated with an acceptable cleaner or detergent", is acceptable.

Your notification has been made a part of the permanent records for this file.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443, or myself at 703-308-6341.

Sincerely,



Marshall Swindell,
Product Manager Team 33,
Regulatory Management Branch I
Antimicrobials Division (7510C)

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

Front Panel
Axen
EPA File Symbol 72977-2
revision March 10, 2004

AXEN®

Stabilized Ionic Silver
Hard Surface Disinfectant

Active Ingredient

Silver*	0.0012%
Citric Acid	4.8400%
<u>Other Ingredients</u>	<u>95.1588%</u>
Total 100.0000%	

* Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA REG. No. 72977-2

EPA EST. No. xxxxx-x-xx

Manufactured by ETI H₂O,
1725 Gillespie Way
El Cajon, CA 92020

Net Vol. XX oz.

Back Panel
Axen
EPA File Symbol 72977-2
Revised March 10, 2004

AXEN® Disinfectant Pump Spray kills bacteria on environmental hard surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) in your home and public places. It eliminates odors on hard nonporous surfaces that you come in contact with everyday. Use AXEN® Disinfectant Pump Spray:

In empty garbage cans	In diaper pails
In pet areas	In empty hampers
In sick rooms	On doorknobs
Under sinks	In bathrooms

Fast/Easy/Effective: AXEN® Disinfectant is effective against *Salmonella chloeraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* organisms. Use anywhere in the home, public places, or boats and vehicles where there are finished surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain). These include areas such as the laundry room, recreation room, kitchen, bedrooms, closets, bathroom, attic and work areas. Interiors of boats and recreational vehicles, AXEN® Disinfectant can be used in such areas as the bathroom, kitchen and anywhere there is a finished surfaces. AXEN® Disinfectant can be used to disinfectant recycling bins, diaper pails, garbage cans and other hard surface containers.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

Prior to application, thoroughly clean all surfaces to be treated with an acceptable cleaner or detergent. For disinfecting, the surface must be completely wet with AXEN® Disinfectant for 10 minutes. The surface may then be wiped dry with a clean unused towel.

STORAGE AND DISPOSAL

Storage	Do not contaminate water, food or feed by storage or disposal.
Disposal	Do not reuse container. Rinse thoroughly before discarding in trash or recycling.



Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

1. Company/Product Number 72977-2	2. EPA Product Manager Marshall Swindell	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Axen	PM# 33	
5. Name and Address of Applicant (Include ZIP Code) ET1 H2O 1725 Gillespie Way El Cajon CA 92020 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(ii), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Notification of Other Labeling Revisions per PR Notice 98-10.

This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-0 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal	
If "Yes" Unit Packaging wgt. No. per container			If "Yes" Package wgt. No. per container	<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 4-32 oz.; 1 - 220 gallon		5. Location of Label Directions <input type="checkbox"/>	
6. Manner in Which Label is Affixed to Product		<input checked="" type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
		<input checked="" type="checkbox"/> Other _____			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name Dolana Blount	Title Regulatory Director	Telephone No. (Include Area Code) 619-596-8600 Ext 105
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Regulatory Director	
4. Typed Name Dolana Blount	5. Date MARCH 2, 2004	

Front Panel
Axen
EPA File Symbol 72977-2
revision March 2, 2004

AXEN®

Stabilized Ionic Silver
Hard Surface Disinfectant

Active Ingredient

Silver*	0.0012%
Citric Acid	4.8400%

<u>Other Ingredients</u>	<u>95.1588%</u>
--------------------------	-----------------

Total 100.0000%

* Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA REG. No. 72977-2

EPA EST. No. xxxxx-x-xx

Manufactured by ETI H₂O,
1725 Gillespie Way
El Cajon, CA 92020

Net Vol. XX oz.

Back Panel
Axen
EPA File Symbol 72977-2
Revised March 2, 2004

AXEN® Disinfectant Pump Spray kills bacteria on environmental hard surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) in your home and public places. It eliminates odors on hard nonporous surfaces that you come in contact with everyday. Use **AXEN® Disinfectant Pump Spray**:

In empty garbage cans	In diaper pails
In pet areas	In empty hampers
In sick rooms	On doorknobs
Under sinks	In bathrooms

Fast/Easy/Effective: **AXEN® Disinfectant** is effective against *Salmonella chloeraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* organisms. Use anywhere in the home, public places, or boats and vehicles where there are finished surfaces (**painted, glazed tile, plastic, metal, glass, glazed porcelain**). These include areas such as the laundry room, recreation room, kitchen, bedrooms, closets, bathroom, attic and work areas. Interiors of boats and recreational vehicles, **AXEN® Disinfectant** can be used in such areas as the bathroom, kitchen and anywhere there is a finished surfaces. **AXEN® Disinfectant** can be used to disinfectant recycling bins, diaper pails, garbage cans and other hard surface containers.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

Prior to application, thoroughly clean all surfaces to be treated. For disinfecting, the surface must be completely wet with **AXEN® Disinfectant** for 10 minutes. The surface may then be wiped dry with a clean unused towel.

STORAGE AND DISPOSAL

Storage	Do not contaminate water, food or feed by storage or disposal.
Disposal	Do not reuse container. Rinse thoroughly before discarding in trash or recycling.



Dolana Blount
<dblount@imspure.co
m>

To: Tony Kish/DC/USEPA/US@EPA
cc: rihanson@bresnan.net
Subject: EPA Reg# 72977-2

03/10/04 03:03 PM

March 10, 2004

Re: Axen, EPA Reg# 72977-2
Notification of other labeling revisions per PR Notice 98-10

Mr. Kish:

Attached per our conversation today is the revised label for our product Axen (EPA Reg# 72977-2). Please replace the label dated March 2, 2004 with the attached label dated March 10, 2004. As requested, I have highlighted the revised pre-cleaning instructions.

Thank you for your assistance. If you need any further information, please contact me directly.

Best Regards,
Dolana

<?xml:namespace prefix = st1 ns = "urn:schemas-microsoft-com:office:smarttags" />Dolana
Blount
ETI H2O
DBlount@imspure.com
619.596.8600, ext. 105

This message is intended for the sole use of the intended recipient. The message and any files transmitted with it may contain material that is confidential and/or legally privileged. Any review, reliance or distribution by others or forwarding without express permission is strictly prohibited. If you are not the intended recipient, please contact the sender and delete all copies and attachments.



031004 Modified Axen Label for E

March 2, 2004

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room 266A, Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202-4501



Attention: Marshall Swindell (PM 33)

Re: Axen, EPA Reg. No. 72977-2
Notification of other labeling revisions per PR Notice 98-10

Dear Mr. Swindell:


As referenced above, we are notifying for clarification of pre-cleaning instructions for "Axen". Upon review of our label by the California Department of Pesticide Registration, we were informed that CDPR did not feel our pre-cleaning statement was not clear for the user. We are making this revision in an effort to more clearly instruct the user of this product of the pre-cleaning step and to satisfy the CDPR for registration purposes. This submission is in full compliance with the notification procedure as identified in PR Notice 98-10.

As required by PR Notice 98-10 for notifications for other labeling revisions, enclosed please find the following:

1. Application Form 8570-1, including the PR Notice 98-10 Certification Statement
2. One copy of the product labeling with the changes highlighted.


Please let me know if you have any questions about the enclosed items.

Best Regards,
ETI H2O


Dolana Blount
Regulatory Director

72977-2

6-26-2001

| | | |
|---|---|---|
|  <p>U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St. S.W.
Washington, D.C. 20460</p> <p>NOTICE OF PESTICIDE:
<u> x </u> Registration
<u> </u> Reregistration

(under FIFRA, as amended)</p> | <p>EPA Reg. Number:

72977-2</p> | <p>Date of Issuance:

JUN 26 2001</p> |
| | <p>Term of Issuance: Conditional</p> | |
| | <p>Name of Pesticide Product:

Axen</p> | |
| <p>Name and Address of Registrant (include ZIP Code):

ETI H₂O
Route 14, Box 1517
Lake City, FL 32054</p> | | |
| <p><small>Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.</small></p> <p><small>On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.</small></p> <p><small>Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.</small></p> <p>This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:</p> <ol style="list-style-type: none"> 1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4. 2. Make the following label changes: <ol style="list-style-type: none"> a. Revise the EPA Registration Number to read, "EPA Reg. No. "72977-2". | | |
| <p>Signature of Approving Official:
Marshall Swindell, PM 33
Regulatory Management Branch I
Antimicrobial Division (7510C)</p> | <p>Date:

JUN 26 2001</p> | |

2
Page 2
EPA Registration No. 72977-2

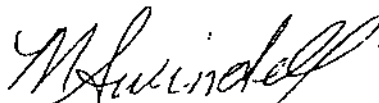
b. Submit two copies of the revised final printed label for the records.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Enclosure

SUBMISSION BAR CODE 5629229 REVIEWER M Teery

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 72977-2 PM 3-3 ACTION CODE 350

DESCRIPTOR Status of Support Data

[] CHILD RESISTANT PACKAGING: [] CERTIFICATION
[] NON-RESIDENTIAL USE ONLY
[] NOT APPLICABLE

REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL

PROPOSED CLASSIFICATION: [] GENERAL [] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

01 13 03

01 20 03

01 22 03

~~METHOD OF SUPPORT~~

~~FORMULATORS EXEMPTION~~

[] CITE ALL
[] SELECTIVE
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

[] SUBMITTED
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA
PACK #

DATE
SENT

DUE
DATE

DATE
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

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STATUS

RESPONSE CODE

37

RESPONSE DATE

FEB 11 2003

Garrison Dental Solutions
Attn: Kevin Walburg
110 DeWitt Lane
Spring Lake, MI 49456

INNOVATIVE

M E D I C A L
S E R V I C E S

a NASDAQ company

Dear Mr. Walburg:

This letter is in response to your offer to pay for the use of our data to support the registration of your H2ProT product with the US EPA.

As a matter of policy, ETI H2O, a division of Innovative Medical Services, does not permit the use of data submitted to the US EPA in support of a registration, but will consider an offer of compensation for data that is not considered Confidential Business Information.

Our data was not generated specifically for silver. All data generated was on the formulated products containing ionic silver as one active ingredient.

ETI H2O is the original data submitter for the technical grade product Axenohl (72977-1) and the formulated end use product Axen (72977-2); thus, the "exclusive use" provisions under FIFRA section 3 (c) (1) (F) protect this data.

ETI H2O believes that OUR product specific data is inappropriate for support of your product; however, if you feel the data may be useful, please contact me for further discussion.

Without additional correspondence, Innovative Medical Services withholds permission for the use of our data under the "exclusive use" provisions of FIFRA.

Please contact Dolana Blount at 619-596-8600 ext. 105 if you wish to discuss.

Sincerely,

INNOVATIVE MEDICAL SERVICES



Gene Auerbach
Chief Operating Officer

Cc: Marshall Swindell, PM33
US EPA, Regulatory Management Branch
Antimicrobial Division (7510C)

NON-FOIA

SUBMISSION BAR CODE SL 17433

REVIEWER K. Levy-Munk

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 72997-2 PM 3.3 ACTION CODE 300

DESCRIPTOR Bold Seal request

☐ CHILD RESISTANT PACKAGING: ☐ CERTIFICATION
☐ NON-RESIDENTIAL USE ONLY
☐ NOT APPLICABLE

REGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL

PROPOSED CLASSIFICATION: ☐ GENERAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

06 18 02

06 18 02

06 18 02

~~METHOD OF SUPPORT~~

~~FORMULATORS EXEMPTION~~

☐ CITE ALL
☐ SELECTIVE
☐ NOT SUBMITTED
☐ NOT APPLICABLE
☐ INCORRECT/RESUB

☐ SUBMITTED
☐ NOT SUBMITTED
☐ NOT APPLICABLE
☐ INCORRECT/RESUB

REVIEW(S) REQUESTED DATA PACK # DATE SENT DUE DATE DATE RETURNED

| | | | | |
|---------------|--|--|--|--|
| CHEMISTRY | | | | |
| EFFICACY | | | | |
| TOXICOLOGY | | | | |
| HED TOX. | | | | |
| ENVIRON. FATE | | | | |
| FISH/WILDLIFE | | | | |
| OTHER | | | | |

STATUS

RESPONSE CODE 38

RESPONSE DATE 6/24/02



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 24th, 2002

I, **Marshall Swindell**, Product Manager 33, Regulatory Management Branch I, Antimicrobials Division, Office of Pesticide Programs, Office of Prevention, Pesticides, and Toxic Substances, United States Environmental Protection Agency (EPA), certify that the pesticide product listed below is, as of the date of this letter, a registered product under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, and that as such, the product may be sold and marketed in the United States of America, as authorized and limited by FIFRA. A true and correct copy of the products label(s) approved by EPA is (are) attached and should accompany this letter.

Registration of this product with EPA also denotes that the registrant listed below is responsible for ensuring full compliance with all laws of the United States of America, or governing jurisdiction, regarding the purchase, sale, application, use, storage, and/or storage and/or disposal of this product.

Further, the recipient of this letter is on notice that the status of the referenced registration and/or the accompanying label may change subsequent to the date of this letter. EPA assumes no responsibility to notify the recipient of this letter of any change in the status of the registration(s) and/or the product label(s) for the product(s) listed below. EPA assumes no responsibility to notify the recipient of this letter of any changes in status of the registration and/or product label for the product listed below.

EPA has issued a registration number for the product(s) listed below to:

ETI H2O

1725 Gillespie Way

El Cajon, CA 92020

EPA Registration Number(s): **72977-2**

Name(s) of Product(s): **Axen**

Marshall Swindell

Product Manager 33

Regulatory Management Branch I

Antimicrobial Division(7510C)

Front Panel
Axen
EPA File Symbol 72977-E
revision June 21, 2001

AXEN®

Stabilized Ionic Silver Hard Surface Disinfectant

Active Ingredient

| | |
|--------------------------|-----------------|
| Silver* | 0.0012% |
| Citric Acid | 4.8400% |
| <u>Other Ingredients</u> | <u>95.1588%</u> |
| Total 100.0000% | |

* Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA REG. No. 72977-E

EPA EST. No. xxxxx-x-xx

Manufactured by ETI H₂O,
Route 14, P. O. Box 1517
Lake City, FL 32024

Net Vol. 36 oz.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 26 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide.
registered under EPA Reg. No.

72977-2

Back Panel
Axen
EPA File Symbol 72977-E
Revised June 21, 2001

AXEN[®] Disinfectant Pump Spray kills bacteria on environmental hard surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) in your home and public places. It eliminates odors on hard nonporous surfaces that you come in contact with everyday. Use AXEN[®] Disinfectant Pump Spray:

In empty garbage cans
In pet areas
In sick rooms
Under sinks

In diaper pails
In empty hampers
On doorknobs
In bathrooms

Fast/Easy/Effective: AXEN[®] Disinfectant is effective against Salmonella chloreraesuis, Staphylococcus aureus, and Pseudomonas aeruginosa organisms. Use anywhere in the home, public places, or boats and vehicles where there are finished surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain). These include areas such as the laundry room, recreation room, kitchen, bedrooms, closets, bathroom, attic and work areas. Interiors of boats and recreational vehicles, AXEN[®] Disinfectant can be used in such areas as the bathroom, kitchen and anywhere there is a finished surfaces. AXEN[®] Disinfectant can be used to disinfectant recycling bins, diaper pails, garbage cans and other hard surface containers.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

Surfaces that are heavy soiled with organic matter must be pre-cleaned prior to using this product. For disinfecting, the surface must be completely wet with AXEN[®] Disinfectant for 10 minutes. The surface may then be wiped dry with a clean unused towel.

STORAGE AND DISPOSAL

| | |
|-----------------|---|
| Storage | Do not contaminate water, food or feed by storage or disposal. |
| Disposal | Do not reuse container. Rinse thoroughly before discarding in trash or recycling. |

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUN 26 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.
72977-2

FAX COVER

~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~ ~~CONFIDENTIAL~~

THIS MESSAGE IS INTENDED ONLY FOR RECEPTION BY THE INDIVIDUAL OR ENTITY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL OR REGULATED IN DISCLOSURE UNDER STATE AND FEDERAL LAWS. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE (COLLECT, IF NECESSARY) AND RETURN THE ORIGINAL COMMUNICATION TO US AT THE ADDRESS BELOW VIA THE US POSTAL SERVICE. THANK YOU.

DATE: 06.18.02TO: Marshall SwindellEPAFAX: 703.308.8481FROM: Dolana BlountETI H2O

PHONE: (619) 596-8600 Ext. 105

FAX: (619) 596-8700

MESSAGE:

Please direct this fax to
Mr. Swindell.

Thank you --
Dolana

Page 1 of 2

VIA FACSIMILE
703-308-8481



June 18, 2002

Marshall Swindell
Product Manager 33, Antimicrobial Division
US EPA
Washington, D.C.

Dear Mr. Swindell:

ETI H2O is requesting two certified letters in reference to our registered products, Axen (72977-2) and Axenohl (72977-1). Please address the first letter to IMS Korea, 3F, Nonhyun-Dong, Kangnam-Ku, Seoul Korea, and the second letter to Innovative Medical Services, 1725 Gillespie Way, El Cajon, CA 92020.

Please send the letters via federal express to our offices at 1725 Gillespie Way, El Cajon, CA 92020. Our Federal Express number is 1626-3497-6.

Should you have any questions, or require additional information, please do not hesitate to contact me directly.

Thank you,
ETI H2O

A handwritten signature in dark ink, appearing to read "Dolara Blount", written over the typed name.

Dolara Blount
Assistant to the President

NON-PQPA

SUBMISSION BAR CODE 5611088REVIEWER MTerryCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 74977-2 PM 33 ACTION CODE 345DESCRIPTOR study

[] CHILD RESISTANT PACKAGING: [] CERTIFICATION
 [] NON-RESIDENTIAL USE ONLY
 [] NOT APPLICABLE

REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL

PROPOSED CLASSIFICATION: [] GENERAL [] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

02 11 0202 14 0202 19 02

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[] CITE-ALL
 [] SELECTIVE
 [] NOT SUBMITTED
 [] NOT APPLICABLE
 [] INCORRECT/RESUB

[] SUBMITTED
 [] NOT SUBMITTED
 [] NOT APPLICABLE
 [] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

17

RESPONSE DATE

APR 26 2002

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

APR 26 2002

ETI H2O Inc.
Route 14, P.O. Box 1517
Lake City, FL 32024

U.S. AGENT: Henry Jacoby
6709 Ilex Court
New Market, MD 21774

Subject: Axenohl
EPA Registration No. 72977-1
Letter Dated March 4, 2002

Axen
EPA Registration NO. 72977-2 ✓
Letter Dated February 11, 2002

The Agency is in receipt of your submitted final Storage-Stability Study in support of the above EPA Registrations under MRID #456232-01. This study was reviewed and found be acceptable. This completes the data requirements for these product registrations.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7510C)

CONCURRENCES

| | | | | | | | | |
|--------|--|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | | |
| IRNAME | | | | | | | | |
| DATE | | | | | | | | |

HENRY JACOBY
REGULATORY CONSULTANT

6709 ILEX COURT
NEW MARKET, MD 21774
865-4333

PHONE: 301-865-9090
FAX: 301-

February 11, 2002

Document Processing Desk (AMEND)
Office of Pesticide Programs (H7507C)
Environmental Protection Agency
Antimicrobial Division
Mr. Marshall Swindell
Ariel Rios Building
1200 Pennsylvania Ave.
Washington, D.C. 20460

Dear Marshall:

Re: SUBMISSION OF Storage Stability Study,
Axen, EPA Reg. NO. 72977-2
ETI H₂O, INC.

ETI H₂O, Inc. has appointed Henry Jacoby to represent it as its agent before the Office of Pesticide Programs of EPA. Please forward all correspondence relative to ETI H₂O, Inc to Henry Jacoby, 6709 Ilex Court, New Market, MD 21774.

This letter transmits the final Storage Stability Study carried out with Axen under warehouse conditions.

Document Control Desk (Amend)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Attn: Marshall Swindell (PM-33)
SUBMISSION OF STORAGE STABILITY STORAGE
Axen
EPA Reg. No. 72977-2

February 11, 2002

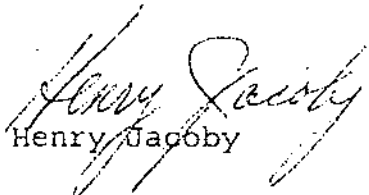
Page 2

Please consider this letter to be the transmittal document for the enclosed study. The studies enclosed are identified below:

| MRID Number | Study Citation |
|-------------|---|
| | Storage Stability Of Axenohl and Axen Under Warehouse Conditions carried out by EPL Bio-Analytical Services (EPL-BAS), 395 N. Memorial Parkway, Harristown, IL 62537, and Submitted by ETI-H20, INC., 1275 Gillespie Way, El Cajon, CA 92020. |

If you have questions regarding this application for registration, please contact me at (301) 865-9090.

Sincerely yours,


Henry Jacoby

cc: G. Duren

HENRY JACOBY
REGULATORY CONSULTANT

6709 ILEX COURT
NEW MARKET, MD 21774
865-4333

PHONE: 301-865-9090
FAX: 301-

February 11, 2002

Document Processing Desk (AMEND)
Office of Pesticide Programs (H7507C)
Environmental Protection Agency
Antimicrobial Division
Mr. Marshall Swindell
Ariel Rios Building
1200 Pennsylvania Ave.
Washington, D.C. 20460

Dear Marshall:

Re: SUBMISSION OF Storage Stability Study
Axen, EPA Req. NO. 72977-2
ETI H₂O, INC.

ETI H₂O, Inc. has appointed Henry Jacoby to represent it as its agent before the Office of Pesticide Programs of EPA. Please forward all correspondence relative to ETI H₂O, Inc to Henry Jacoby, 6709 Ilex Court, New Market, MD 21774.

This letter transmits the final Storage Stability Study carried out with Axen under warehouse conditions.

Document Control Desk (Amend)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Attn: Marshall Swindell (PM-33)
SUBMISSION OF STORAGE STABILITY STORAGE
Axen
EPA Reg. No. 72977-2

February 11, 2002

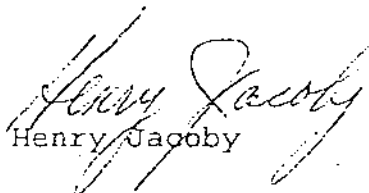
Page 2

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If you have questions regarding this application for registration, please contact me at (301) 865-9090.

Sincerely yours,


Henry Jacoby

cc: G. Duren

HENRY JACOBY
REGULATORY CONSULTANT

6709 ILEX COURT
NEW MARKET, MD 21774
865-4333

PHONE: 301-865-9090
FAX: 301-

February 11, 2002

Document Processing Desk (AMEND)
Office of Pesticide Programs (H7507C)
Environmental Protection Agency
Antimicrobial Division
Mr. Marshall Swindell
Ariel Rios Building
1200 Pennsylvania Ave.
Washington, D.C. 20460

Dear Marshall:

Re: SUBMISSION OF Storage Stability Study
Axen, EPA Reg. NO. 72977-2
ETI H₂O, INC.

ETI H₂O, Inc. has appointed Henry Jacoby to represent it as its agent before the Office of Pesticide Programs of EPA. Please forward all correspondence relative to ETI H₂O, Inc to Henry Jacoby, 6709 Ilex Court, New Market, MD 21774.

This letter transmits the final Storage Stability Study carried out with Axen under warehouse conditions.

Document Control Desk (Amend)
Office of Pesticide Programs
U. S. Environmental Protection Agency
Attn: Marshall Swindell (PM-33)
SUBMISSION OF STORAGE STABILITY STORAGE
Axen
EPA Reg. No. 72977-2

February 11, 2002

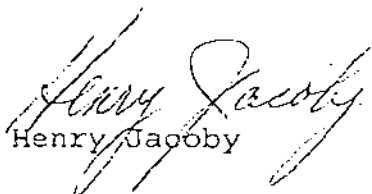
Page 2

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| MRID Number | Study Citation |
|-------------|---|
| | Storage Stability Of Axenohl and Axen Under Warehouse Conditions carried out by EPL Bio-Analytical Services (EPL-BAS), 395 N. Memorial Parkway, Harristown, IL 62537, and Submitted by ETI-H20, INC., 1275 Gillespie Way, El Cajon, CA 92020. |

If you have questions regarding this application for registration, please contact me at (301) 865-9090.

Sincerely yours,


Henry Jacoby

cc: G. Duren

SUBMISSION BAR CODE #

624629

REVIEWER

KL

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO.

72977-2

PM

33

ACTION CODE

333

DESCRIPTOR

Telephone Call From Consultant

☐ CHILD RESISTANT PACKAGING:☐ CERTIFICATION☐ NON-RESIDENTIAL USE ONLY☐ NOT APPLICABLEREGISTRATION TYPE: ☐ CONDITIONAL☐ UNCONDITIONALPROPOSED CLASSIFICATION: ☐ GENERAL☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

10 / 9 / 01

10 / 9 / 01

10 / 9 / 01

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL☐ SUBMITTED☐ SELECTIVE☐ NOT SUBMITTED☐ NOT SUBMITTED☐ NOT APPLICABLE☐ NOT APPLICABLE☐ INCORRECT/RESUB☐ INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

17

RESPONSE DATE

10/12/01



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OCT 12 2001

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

Henry M. Jacoby
ETI-H2O, Inc.
1725 Gillespie Way
El Cajon, CA 92020

Subject: AXEN
EPA Registration Number 72977-2
Your Notification Dated October 9th, 2001
EPA Received Date October 9th, 2001

Dear Mr. Jacoby:

The notification referred to above, submitted under the provisions of FIFRA Section 3(c)9, to add the alternate brand name "Clean Kill". Based on a review of the submitted materials, the following comments apply.

After further consideration the Agency has determined that the notification for the brand name is acceptable. This Notification Has been made part of the permanent records for this file.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,

A handwritten signature in cursive script, appearing to read "M. Swindell".

Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division (7510C)

KAREN,

WOULD YOU PLEASE PULL REG# 72977-2 FROM THE
FILEROOM. THE COMPANY PREVIOUSLY REQUESTED
APPROVAL FOR THE ADDITIONAL BRAND NAME
"CLEAN KILL", AND WE TURNED THEM DOWN.

SINCE THEN IT WAS DETERMINED THAT THE NAME
HAS BEEN APPROVED FOR OTHER PRODUCTS.
PLEASE SETUP AN ACCEPTANCE LETTER SAYING
AFTER FURTHER CONSIDERATION THE AGENCY HAS
DETERMINED THAT THE NOTIFICATION FOR THE
BRAND NAME IS ACCEPTABLE.

USE ACTION CODE 333 WITH 10/09/01 AS THE
RESUBMISSION, EPA RECEIVE, AND PM RECEIVE
DATES. USE "TELEPHONE CALL FROM CONSULTANT"
AS THE PRODUCT DESCRIPTOR.

THANKS MARSHALL

10/09/01

REVIEWER S. Gordon

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 71977-2 PM 33 ACTION CODE 332

| DESCRIPTOR | Alternate Brand Name |
|------------|----------------------|
|------------|----------------------|

[] CHILD RESISTANT PACKAGING: [] CERTIFICATION-----
[] NON-RESIDENTIAL USE ONLY
[] NOT APPLICABLE

REGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL

PROPOSED CLASSIFICATION: ☐ GENERAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE:

| | | |
|----|----|----|
| 09 | 07 | 01 |
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| 09 | 12 | 81 |
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~~METHOD OF SUPPORT~~

FORMULATORS: EXEMPTION

[] CITE-ALL
[] SELECTIVE
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB.

[] SUBMITTED
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA
PACK #

DATE
SENT-

DUE
DATE-

DATE ..
RETURNED ..

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

12

RESPONSE DATE

SEP 27 2001

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 27 2001

ETI-H20, Inc.
1725 Gillespie Way
El Cajon, CA 92020

Attention: Henry M. Jacoby, Agent
6709 Ilex Court
New Market, MD 21774

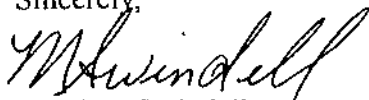
Subject: Axen
EPA Registration No. 72977-2
Notification Dated September 7, 2001

This will acknowledge receipt of your notification, submitted under the provisions of FIFRA Section 3(c)9, to add the alternate brand name "Clean Kill." Based on a review of the submitted material, the following comments apply.

The brand name is false and misleading therefore it is unacceptable and the notification has been made part of the records for this file. The proposed name can infer that your product is both a cleaner and disinfectant.

If you have any question concerning this letter, please contact Solange Garvey at (703) 308-8911.

Sincerely,



Marshall Swindell,
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division (7510C)

| CONCURRENCES | | | | | | | |
|--------------|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
| DATE | | | | | | | |

HENRY JACOBY
REGULATORY CONSULTANT

6709 ILEX COURT
NEW MARKET, MD 21774

PHONE: 301-865-9090
FAX: 301-865-4333

September 7, 2001

Environmental Protection Agency
Office of Pesticide Programs
Antimicrobial Division (H7507C)
Mr. Marshall Swindell
USEPA Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Marshall:

Re: Notification of Alternate Brand Name
Axen, EPA File Symbol 72977-2
ETI H₂O, INC.

ETI H₂O, Inc. has appointed Henry Jacoby to represent it as its agent before the Office of Pesticide Programs of EPA. Please forward all correspondence relative to ETI H₂O, Inc to Henry Jacoby, 6709 Ilex Court, New Market, MD 21774.

This letter transmits a notification for an alternate brand name for the product Axen. Axen is the primary brand name and Clean Kill will be an alternate brand name. No other changes have been made to the formulation or the label.

Sincerely yours,


Henry Jacoby

cc: G. Duren



United States
Environmental Protection Agency
Washington DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|--|---|--|
| Company/Product Number
72977-2 | 2. EPA Product Manager
Marshall Swindell | 3. Proposed Classification
<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| Company/Product (Name)
Axen | PM#
33 | |
| 5. Name and Address of Applicant (Include ZIP Code)
ETI-H2O, Inc.
1725 Gillespie Way
El Cajon, CA 92020
<input checked="" type="checkbox"/> Check if this is a new address | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____ |

Section - II

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input checked="" type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)
This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U. S. C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 91-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under section 12 and 14 of FIFRA.

Section - III

| | | | | | |
|--|--|---|--|--|-------------------|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging
<input type="checkbox"/> Yes
<input checked="" type="checkbox"/> No | Unit Packaging
<input type="checkbox"/> Yes
<input checked="" type="checkbox"/> No | Water Soluble Packaging
<input type="checkbox"/> Yes
<input checked="" type="checkbox"/> No | <input checked="" type="checkbox"/> Metal
<input checked="" type="checkbox"/> Plastic
<input type="checkbox"/> Glass
<input type="checkbox"/> Paper
<input type="checkbox"/> Other (Specify) _____ | | |
| * Certification must be submitted | | If "Yes" Unit Packaging wgt. | No. per container | If "Yes" Package wgt. | No. per container |
| Location of Net Contents Information
<input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container
32 oz | | 5. Location of Label Directions
<input checked="" type="checkbox"/> On Label
<input type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product
<input checked="" type="checkbox"/> Lithograph
<input type="checkbox"/> Paper glued
<input type="checkbox"/> Stenciled | | | <input type="checkbox"/> Other _____ | | |

Section - IV

| | | |
|--|----------------------------------|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | |
| Name
Henry M. Jacoby | Title
Agent | Telephone No. (Include Area Code)
301-865-9090 |
| Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | 6. Date Application Received
(Stamped) |
| Signature
 | 3. Title
Agent, ETI-H2O, Inc. | |
| Typed Name
Henry Jacoby | 5. Date
9/7/01 | |

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 72977-2 PM 33 ACTION CODE 302
 DESCRIPTOR Revised Label

[] CHILD RESISTANT PACKAGING: [] CERTIFICATION
 [] NON-RESIDENTIAL USE ONLY
 [] NOT APPLICABLE

REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL

PROPOSED CLASSIFICATION: [] GENERAL [] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

06 22 01

06 25 01

06 27 01

~~METHOD OF SUPPORT~~

~~FORMULATORS EXEMPTION~~

[] CITE-ALL
 [] SELECTIVE
 [] NOT SUBMITTED
 [] NOT APPLICABLE
 [] INCORRECT/RESUB

[] SUBMITTED
 [] NOT SUBMITTED
 [] NOT APPLICABLE
 [] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA
PACK #

DATE
SENT

DUE
DATE

DATE
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

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STATUS

Information filed in Ticket

RESPONSE CODE

37

RESPONSE DATE

9/14/01

HENRY JACOBY
REGULATORY CONSULTANT

6709 ILEX COURT
NEW MARKET, MD 21774

PHONE: 301-865-9090
FAX: 301-865-4333

June 22, 2001

Environmental Protection Agency
Office of Pesticide Programs
Antimicrobial Division (H7507C)
Mr. Marshall Swindell
Room 308H Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Marshall:

Re: RESUBMISSION OF APPLICATION FOR NEW REGISTRATION
Axen, EPA File Symbol 72977-E
ETI H₂O, INC.

ETI H₂O, Inc. has appointed Henry Jacoby to represent it as its agent before the Office of Pesticide Programs of EPA. Please forward all correspondence relative to ETI H₂O, Inc to Henry Jacoby, 6709 Ilex Court, New Market, MD 21774.

This letter is in response to the Agency's letter of June 21, 2001, which requested several labeling changes. This letter transmits labeling revised as per your letter.

The label has been revised as follows:

1. The statements "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling." has been added to the label;
2. The term Streptococcus has been removed from the label;
3. The word germ has been deleted;
4. The word "glazed" has been added before porcelain and tile.
5. The section under Fast/Easy/Effective has been revised to better describe the use areas;

Office of Pesticide Programs
U. S. Environmental Protection Agency
Attn: Marshall Swindell, PM 33
RESUBMISSION FOR NEW REGISTRATION
Axen
EPA FILE SYMBOL 72977-E

June 22, 2001

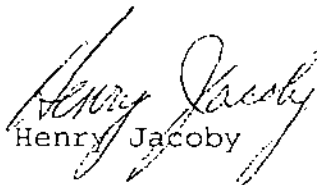
Page 2

6. The label use directions have been revised by adding a statement requiring pre-cleaning of heavy soiled (with organic matter) surfaces;
7. The label has been revised to use the complete scientific name of the organisms. *Staphylococcus aureus* has also been added since testing was carried out with that organism also.
8. The label use directions have been revised by revising 1 minute to 10 minutes and by adding a statement requiring the surface to be completely wet for disinfecting.

CONTENT OF SUBMISSION

5 copies of labeling

Sincerely yours,


Henry Jacoby

cc: A. Arata
E. Woolson

Front Panel
Axen
EPA File Symbol 72977-E
revision June 21, 2001

AXEN®

Stabilized Ionic Silver
Hard Surface Disinfectant

Active Ingredient

| | |
|--------------------------|-----------------|
| Silver* | . 0.0012% |
| Citric Acid | 4.8400% |
| <u>Other Ingredients</u> | <u>95.1588%</u> |
| Total 100.0000% | |

* Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA REG. No. 72977-E

EPA EST. No. xxxxx-x-xx

Manufactured by ETI H₂O,
Route 14, P. O. Box 1517
Lake City, FL 32024

Net Vol. 36 oz.

Back Panel
Axen
EPA File Symbol 72977-E
Revised June 21, 2001

AXEN[®] Disinfectant Pump Spray kills bacteria on environmental hard surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) in your home and public places. It eliminates odors on hard nonporous surfaces that you come in contact with everyday. Use AXEN[®] Disinfectant Pump Spray:

In empty garbage cans
In pet areas
In sick rooms
Under sinks

In diaper pails
In empty hampers
On doorknobs
In bathrooms

Fast/Easy/Effective: AXEN[®] Disinfectant is effective against *Salmonella chloreraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* organisms. Use anywhere in the home, public places, or boats and vehicles where there are finished surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain). These include areas such as the laundry room, recreation room, kitchen, bedrooms, closets, bathroom, attic and work areas. Interiors of boats and recreational vehicles, AXEN[®] Disinfectant can be used in such areas as the bathroom, kitchen and anywhere there is a finished surfaces. AXEN[®] Disinfectant can be used to disinfectant recycling bins, diaper pails, garbage cans and other hard surface containers.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

Surfaces that are heavy soiled with organic matter must be pre-cleaned prior to using this product. For disinfecting, the surface must be completely wet with AXEN[®] Disinfectant for 10 minutes. The surface may then be wiped dry with a clean unused towel.

STORAGE AND DISPOSAL

| | |
|----------|---|
| Storage | Do not contaminate water, food or feed by storage or disposal. |
| Disposal | Do not reuse container. Rinse thoroughly before discarding in trash or recycling. |

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 72977-2 PM 33 ACTION CODE 302DESCRIPTOR Final Printed Labels

[] CHILD RESISTANT PACKAGING: [] CERTIFICATION
[] NON-RESIDENTIAL USE ONLY
[] NOT APPLICABLE

REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL

PROPOSED CLASSIFICATION: [] GENERAL [] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

| | | |
|----|----|----|
| 07 | 05 | 01 |
|----|----|----|

| | | |
|----|----|----|
| 07 | 09 | 01 |
|----|----|----|

| | | |
|----|----|----|
| 07 | 11 | 01 |
|----|----|----|

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[] CITE-ALL
[] SELECTIVE
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

[] SUBMITTED
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

7

RESPONSE DATE

7/31/01

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 31 2001

ETI H₂O
Route 14
P.O. Box 1517
Lake City, FL 32024

MAIL TO: Henry Jacoby, Agent
6709 Ilex Court
New Market, MD 21774

Subject: Axen
EPA Registration No. 72977-2
Letter Dated July 5, 2001

The Agency is in receipt of your submitted final printed label based on the previously accepted draft label dated June 26, 2001. The label has been placed in your product registration file and not reviewed in accordance with PR Notice 82-2.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,

Martha Swindell

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7505C)

| CONCURRENCES | | | | | | | |
|--------------|--|--|--|--|--|--|--|
| SYMBOL | | | | | | | |
| SURNAME | | | | | | | |
| DATE | | | | | | | |

HENRY JACOBY
REGULATORY CONSULTANT

6709 ILEX COURT
NEW MARKET, MD 21774

PHONE: 301-865-9090
FAX: 301-865-4333

July 5, 2001

Environmental Protection Agency
Office of Pesticide Programs
Antimicrobial Division (H7507C)
Mr. Marshall Swindell
Ariel Rios Building
1200 Pennsylvania Ave.
Washington, D.C. 20460

Dear Marshall:

Re: RESUBMISSION OF Final Printed Labeling
Axen, EPA File Symbol 72977-2
ETI H₂O, INC.

ETI H₂O, Inc. has appointed Henry Jacoby to represent it as its agent before the Office of Pesticide Programs of EPA. Please forward all correspondence relative to ETI H₂O, Inc to Henry Jacoby, 6709 Ilex Court, New Market, MD 21774.

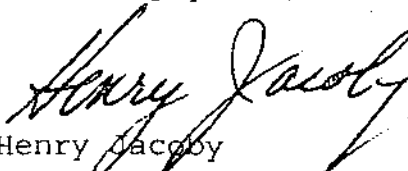
This letter is in response to the Agency's Notice of Pesticide Registration, dated June 26, 2001, which requested two copies of final printed labeling. This letter transmits copies of the finished labels.

The label has been revised by revising the EPA Registration Number to read EPA Reg. No. 72977-2

CONTENT OF SUBMISSION

2 copies of final labeling

Sincerely yours,


Henry Jacoby

cc: A. Arata
E. Woolson



AXEN[®]

Stabilized Ionic Silver
Hard Surface Disinfectant

Active Ingredient

Silver* 0.0012%

Citric Acid 4.8400%

Other Ingredients

95.1588%

Total 100.0000%

* Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA REG. No. 72977-2

EPA EST. No. 72977-FL-1

Manufactured by ETI H₂O,
Route 14, P. O. Box 1517
Lake City, FL 32024

Net Vol. 36 oz.

NOT REVIEWED

**In Accordance with PR Notice 02-20
Based on Draft Labeling Dated**

47

AXEN® Disinfectant Pump Spray kills bacteria on environmental hard surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) in your home and public places. It eliminates odors on hard nonporous surfaces that you come in contact with everyday. Use **AXEN® Disinfectant Pump Spray**:

In empty garbage cans
In pet areas
In sick rooms
Under sinks

In diaper pails
In empty hampers
On doorknobs
In bathrooms

Fast/Easy/Effective: **AXEN® Disinfectant** is effective against *Salmonella chloreraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* organisms. Use anywhere in the home, public places, or boats and vehicles where there are finished surfaces (**painted, glazed tile, plastic, metal, glass, glazed porcelain**). These include areas such as the laundry room, recreation room, kitchen, bedrooms, closets, bathroom, attic and work areas. Interiors of boats and recreational vehicles, **AXEN® Disinfectant** can be used in such areas as the bathroom, kitchen and anywhere there is a finished surfaces. **AXEN® Disinfectant** can be used to disinfectant recycling bins, diaper pails, garbage cans and other hard surface containers.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

Surfaces that are heavy soiled with organic matter must be pre-cleaned prior to using this product. For disinfecting, the surface must be completely wet with **AXEN® Disinfectant** for 10 minutes. The surface may then be wiped dry with a clean unused towel.

STORAGE AND DISPOSAL

| | |
|-----------------|---|
| Storage | Do not contaminate water, food or feed by storage or disposal. |
| Disposal | Do not reuse container. Rinse thoroughly before discarding in trash or recycling. |

AXEN®

Stabilized Ionic Silver
Hard Surface Disinfectant

Active Ingredient

Silver* 0.0012%

Citric Acid 4.8400%

Other Ingredients 95.1588%

Total 100.0000%

* Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA REG. No. 72977-2

EPA EST. No. 72977-FL-1

Manufactured by ETI H₂O,
Route 14, P. O. Box 1517
Lake City, FL 32024

Net Vol. 36 oz.

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In empty garbage cans
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STORAGE AND DISPOSAL

| | |
|-----------------|---|
| Storage | Do not contaminate water, food or feed by storage or disposal. |
| Disposal | Do not reuse container. Rinse thoroughly before discarding in trash or recycling. |

SUBMISSION BAR CODE # 5599534 REVIEWER MTerryCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FOIPA

FILE SYMBOL/REG NO. 72977-E PM 3.3 ACTION CODE 189DESCRIPTOR Resubmitted Application

[] CHILD RESISTANT PACKAGING: [] CERTIFICATION
[] NON-RESIDENTIAL USE ONLY
[] NOT APPLICABLE

REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL

PROPOSED CLASSIFICATION: [] GENERAL [] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

| | | |
|----|----|----|
| 06 | 22 | 01 |
|----|----|----|

| | | |
|----|----|----|
| 06 | 22 | 01 |
|----|----|----|

| | | |
|----|----|----|
| 06 | 22 | 01 |
|----|----|----|

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[] CITE-ALL
[] SELECTIVE
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

[] SUBMITTED
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE 18

RESPONSE DATE

JUN 25 2001



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Registration Division (H7505C)
401 "M" St., S.W.
Washington, D.C. 20460

EPA Reg. Number:

72977-2

Date of Issuance:

JUN 26 2001

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:

Axen

Name and Address of Registrant (include ZIP Code):

ETI H₂O
Route 14, Box 1517
Lake City, FL 32054

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA sec. 3(c)(5) when the Agency requires all registrants of similar products to submit such data; and submit acceptable responses required for reregistration of your product under FIFRA section 4.

2. Make the following label changes:

a. Revise the EPA Registration Number to read, "EPA Reg. No. "72977-2".

Signature of Approving Official:

Marshall Swindell, PM 33
Regulatory Management Branch I
Antimicrobial Division (7510C)

Date:

JUN 26 2001

Page 2

EPA Registration No. 72977-2

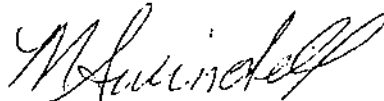
b. Submit two copies of the revised final printed label for the records.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,

A handwritten signature in dark ink, appearing to read "M. Swindell", written in a cursive style.

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7510C)

Enclosure

Front Panel
Axen
EPA File Symbol 72977-E
revision June 21, 2001

AXEN®

Stabilized Ionic Silver Hard Surface Disinfectant

Active Ingredient

Silver* 0.0012%

Citric Acid 4.8400%

Other Ingredients 95.1588%

Total 100.0000%

* Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA REG. No. 72977-E

EPA EST. No. xxxxx-x-xx

Manufactured by ETI H₂O,
Route 14, P. O. Box 1517
Lake City, FL 32024

Net Vol. 36 oz.

ACCEPTED
with COMMENTS
in EPA Letter Dated:

JUN 26 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide.
registered under EPA Reg. No.

72977-E

Back Panel
Axen
EPA File Symbol 72977-E
Revised June 21, 2001

AXEN[®] Disinfectant Pump Spray kills bacteria on environmental hard surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain) in your home and public places. It eliminates odors on hard nonporous surfaces that you come in contact with everyday. Use AXEN[®] Disinfectant Pump Spray:

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In sick rooms
Under sinks

In diaper pails
In empty hampers
On doorknobs
In bathrooms

Fast/Easy/Effective: AXEN[®] Disinfectant is effective against *Salmonella chloreraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa* organisms. Use anywhere in the home, public places, or boats and vehicles where there are finished surfaces (painted, glazed tile, plastic, metal, glass, glazed porcelain). These include areas such as the laundry room, recreation room, kitchen, bedrooms, closets, bathroom, attic and work areas. Interiors of boats and recreational vehicles, AXEN[®] Disinfectant can be used in such areas as the bathroom, kitchen and anywhere there is a finished surfaces. AXEN[®] Disinfectant can be used to disinfectant recycling bins, diaper pails, garbage cans and other hard surface containers.

Directions for Use

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling

Surfaces that are heavy soiled with organic matter must be pre-cleaned prior to using this product. For disinfecting, the surface must be completely wet with AXEN[®] Disinfectant for 10 minutes. The surface may then be wiped dry with a clean unused towel.

STORAGE AND DISPOSAL

| | |
|-----------------|--|
| Storage | Do not contaminate water, food or feed by storage or disposal. |
| Disposal | Do not reuse container. Rinse thoroughly before discarding in trash or recycling.. |

ACCEPTED
with COMMENTS
in EPA Letter Dated:
JUN 26 2001

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

72977-2

**HENRY JACOBY
REGULATORY CONSULTANT**

FACSIMILE COVER PAGE

To: Attn: Marshall Swindell/Martha Terry

Fax #: 1-703-308-8481

Company: ETI H2O, Inc.

From: Henry Jacoby

Fax #: 301/865-4333

Tel#: 301-865-9090

Subject: Axen and Axenohl Resubmissions

Sent: June 22, 2001

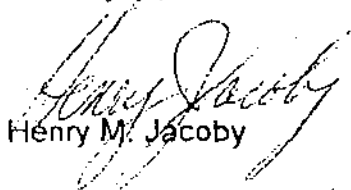
Pages: 11 (including
cover)

MESSAGE:

Marshall/Martha,

I am faxing copies of resubmissions for Axenohl, EPA File Symbol 79277-R (revised label and CFR) and for Axen, EPA File Symbol 79277-E (label revisions). The original will be Fed-Ex ed to you for delivery by Monday A.M.. I hope that you can work with the faxed copies to issue the registrations. Can you fax me a copy of registration notice and stamped label when approved.

Thank you,


Henry M. Jacoby

THE INFORMATION IN THIS FAX IS CONFIDENTIAL AND PRIVILEGED INFORMATION OR WORK PRODUCT. THE INFORMATION IS INTENDED ONLY FOR THE USE OF THE PERSON OR ENTITY TO WHOM IT IS ADDRESSED. IF YOU ARE NOT THE INTENDED RECIPIENT OR THE EMPLOYEE OR AGENT RESPONSIBLE TO DELIVER IT TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY USE, DISSEMINATION, DISTRIBUTION, OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THE FAX IN ERROR, PLEASE IMMEDIATELY NOTIFY US BY TELEPHONE, AND RETURN THE ORIGINAL MESSAGE TO US AT 6709 ILEX COURT, NEW MARKET, MD 21774-2907 VIA THE US POSTAL SERVICE. THANK YOU.

HENRY JACOBY
REGULATORY CONSULTANT

6709 ILEX COURT
NEW MARKET, MD 21774

PHONE: 301-865-9090
FAX: 301-865-4333

June 22, 2001

Environmental Protection Agency
Office of Pesticide Programs
Antimicrobial Division (H7507C)
Mr. Marshall Swindell
Room 308H Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Marshall:

Re: RESUBMISSION OF APPLICATION FOR NEW REGISTRATION
Axen, EPA File Symbol 72977-E
ETI H₂O, INC.

ETI H₂O, Inc. has appointed Henry Jacoby to represent it as its agent before the Office of Pesticide Programs of EPA. Please forward all correspondence relative to ETI H₂O, Inc to Henry Jacoby, 6709 Ilex Court, New Market, MD 21774.

This letter is in response to the Agency's letter of June 21, 2001, which requested several labeling changes. This letter transmits labeling revised as per your letter.

The label has been revised as follows:

1. The statements "It is a violation of Federal Law to use this product in a manner inconsistent with its labeling." has been added to the label;
2. The term Streptococcus has been removed from the label;
3. The word germ has been deleted;
4. The word "glazed" has been added before porcelain and tile.
5. The section under **Fast/Easy/Effective** has been revised to better describe the use areas;

Office of Pesticide Programs
U. S. Environmental Protection Agency
Attn: Marshall Swindell, PM 33
RESUBMISSION FOR NEW REGISTRATION
Axen
EPA FILE SYMBOL 72977-E

June 22, 2001

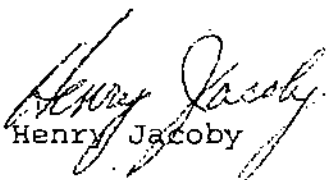
Page 2

6. The label use directions have been revised by adding a statement requiring pre-cleaning of heavy soiled (with organic matter) surfaces;
7. The label has been revised to use the complete scientific name of the organisms. *Staphylococcus aureus* has also been added since testing was carried out with that organism also.
8. The label use directions have been revised by revising 1 minute to 10 minutes and by adding a statement requiring the surface to be completely wet for disinfecting.

CONTENT OF SUBMISSION

5 copies of labeling

Sincerely yours,


Henry Jacoby

cc: A. Arata
E. Woolson

HENRY JACOBY
REGULATORY CONSULTANT

6709 ILEX COURT
NEW MARKET, MD 21774

PHONE: 301-865-9090
FAX: 301-865-4333

May 2, 2001.

Environmental Protection Agency
Office of Pesticide Programs
Antimicrobial Division (H7507C)
Mr. Marshall Swindell
Room 308H Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Marshall:

Re: RESUBMISSION OF APPLICATION FOR NEW REGISTRATION
Axen, EPA File Symbol 72977-E
ETI H₂O, INC.

ETI H₂O, Inc. has appointed Henry Jacoby to represent it as its agent before the Office of Pesticide Programs of EPA. Please refer to the enclosed letter of appointment signed by Andrew Arata, President of ETI H₂O, Inc.

Please forward all correspondence relative to ETI H₂O, Inc to Henry Jacoby, 6709 Ilex Court, New Market, MD 21774.

This letter is in response to the Agency's letter of March 26, 2001 which delineated several deficiencies with the application.

Regarding the inhalation toxicity test, ETI H₂O, Inc is requesting a waiver from the requirement. See the attachment for further information.

I believe the confusion over the efficacy study to which you refer to in your letter of November 29, 2000 has been cleared up as a result of our meeting with your staff. It is my understanding the AOAC use dilution study (MRID No. 45016906) has been put into review.

Enclosed is a data matrix for silver and citric acid. The method of support for this application is the "Selective Method." The

Office of Pesticide Programs
U. S. Environmental Protection Agency
Attn: Marshall Swindell, PM 33
RESUBMISSION FOR NEW REGISTRATION
Axen
EPA FILE SYMBOL 72977-E

05/02/01

Page 2

application relies on the data references given in the Agency's Reregistration Eligibility Document (RED) for silver and citric acid. These documents relied on information in the public literature to support the reregistration of silver and citric acid. Since the proposed uses of AXEN is not substantially different from the currently registered uses, the waivers given in the RED should apply to the toxicity and exposure data requirements needed to support this application. The only exception to this is the two avian studies, which were submitted by Mason Chemical Company. ETI H₂O has sent a offer to pay letter to Mason Chemical Company.

CONTENT OF SUBMISSION

1. EPA Form 8570-1 (EPA File Symbol 72977-E).
2. EPA Form 8570-4 (two original copies).
3. EPA Form 8570-34 (Selective method, using cited data).
4. EPA Form 8570 (agency internal copy and public file copy) for silver, citric acid and citric acid and silver.
5. Request for a Waiver from Acute Inhalation Testing with supporting report.
6. Five (5) copies of draft labeling.
7. Agent appointment letter of April 27, 2001

Sincerely yours,


Henry Jacoby



United States
Environmental Protection Agency
Washington DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|--|---|--|
| 1. Company/Product Number
72977-E | 2. EPA Product Manager
Marshall Swindell | 3. Proposed Classification
<input checked="" type="checkbox"/> None <input type="checkbox"/> Restrict |
| 4. Company/Product (Name)
Axen | PM#
33 | |
| 5. Name and Address of Applicant (Include ZIP Code)
ETI H2O
Route 14, Box 1517
Lake City, FL 32034
<input type="checkbox"/> Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(2)(b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____ | |

Section - II

| | |
|---|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input checked="" type="checkbox"/> Resubmission in response to Agency letter dated 3/26/01 | <input type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

| | | | | | |
|--|---|---|---|--|--|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging
<input checked="" type="checkbox"/> Yes
<input checked="" type="checkbox"/> No

* Certification must be submitted | Unit Packaging
<input checked="" type="checkbox"/> Yes
<input type="checkbox"/> No
If "Yes"
Unit Packaging wgt. _____ No. per container _____ | Water Soluble Packaging
<input checked="" type="checkbox"/> Yes
<input type="checkbox"/> No
If "Yes"
Package wgt. _____ No. per container _____ | <input checked="" type="checkbox"/> Metal
<input type="checkbox"/> Plastic
<input type="checkbox"/> Glass
<input type="checkbox"/> Paper
<input type="checkbox"/> Other (Specify) _____ | | |
| 3. Location of Net Contents Information
<input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container | | 5. Location of Label Directions
<input checked="" type="checkbox"/> On Label
<input type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product
<input checked="" type="checkbox"/> Lithograph
<input type="checkbox"/> Paper glued
<input type="checkbox"/> Stenciled | | <input type="checkbox"/> Other _____ | | | |

Section - IV

| | | |
|---|----------------|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | |
| Name
Henry Jacoby | Title
Agent | Telephone No. (Include Area Code)
(301) 865-9090 |
| 2. Signature
 | | 6. Date Application Received
(Stamped) |
| 3. Title
Agent, ETI H2O | | |
| 4. Typed Name
Henry Jacoby, Agent | | |
| 5. Date
5/2/01 | | |

REVIEWER MT

DESCRIPTOR Response to Agency ltr dated 3/26/01

[] CHILD RESISTANT PACKAGING: [] CERTIFICATION
[] NON-RESIDENTIAL USE ONLY
[] NOT APPLICABLE

PROPOSED CLASSIFICATION: [] GENERAL [] RESTRICTED USE

PM RECEIVE DATE..

| | | |
|----|----|----|
| 25 | 09 | 01 |
|----|----|----|

FORMULATORS EXEMPTION

```
[ ] SUBMITTED
[ ] NOT SUBMITTED
[ ] NOT APPLICABLE
[ ] INCORRECT/RESUB
```

DATE ..
RETURNED

OTHER

[illegible]

STATUS

JUN 21 2001

REFUGEE CODE

RESPONSE DATE

JUN 21 2001

ETI H₂O
Route 14, Box 1517
Lake City, FL 32054

Attention: Henry Jacoby, Agent

Subject: Axen
EPA File Symbol 72977-E
Letters Dated April 24, 2001 and May 2, 2001

The Agency has determined that your application is incomplete. Before the Agency can continue processing your application you must satisfy the deficiencies below.

LABELING

Submit five (5) copies of draft labeling revised in accordance with the following instructions.

1. Include the following statement directly below the "Directions For Use" heading.

"It is a violation of Federal Law to use this product in a manner inconsistent with its labeling."

2. No efficacy data were submitted for any *Streptococcus* spp. The term "*Streptococcus*" must be removed.

4. Refer to the Efficacy Review for additional labeling comments.

EFFICACY

The submitted efficacy data were found to be acceptable. However, refer to the attached efficacy review under "LABELING" for labeling deficiencies and revise accordingly.

ACUTE TOXICITY

As per the Agency's letter dated March 15, 2001, the following acute toxicity data (Oral, Sensitization, Dermal, Eye Irritation, Skin Irritation) studies are acceptable. A waiver request for the Acute Inhalation study was also found acceptable. Please refer to the attached toxicity

| CONCURRENCES | | | | | | | |
|--------------|---|--|--|--|--|--|--|
| SYMBOL | review for the results of the acute inhalation study. | | | | | | |
| SURNAME | | | | | | | |
| DATE | | | | | | | |

Page 2

PRODUCT CHEMISTRY/CSF

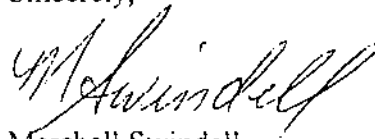
The Product Chemistry Data was found to be acceptable. The Confidential Statement of Formula (CSF) dated June 2, 2001 is in compliance with PR Notice 92-1, agrees with the label and is acceptable.

However, on your CSF, the total weight in item #17 must be included. Submit a new CSF for our records.

This letter does not constitute registration and the product may not be lawfully marketed until all the required information has been submitted for review and found acceptable.

If you have any questions concerning this letter, please contact Martha Terry at (703) 305-6982.

Sincerely,

A handwritten signature in dark ink, appearing to read "M. Swindell", written over the typed name.

Marshall Swindell
Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7505C)

Attachment

Front Panel
Axen
EPA File Symbol 72977-E
revision May 2, 2001

AXEN®

Stabilized Ionic Silver
Hard Surface Disinfectant

Active Ingredient

Silver*..... 0.0012%
Citric Acid..... 4.8400%

Other Ingredients.....95.1588%

Total 100.0000%

* Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA REG. No. 72977-E

EPA EST. No. xxxxx-x-xx

Manufactured by ETI H₂O,
Route 14, P. O. Box1517
Lake City, FL 32024

Net Vol. 36 oz.

Back Panel
Axen
EPA File Symbol 72977-E
Revised May 2, 2001

AXEN[®] Disinfectant Pump Spray kills bacteria on environmental hard surfaces (painted, tile, plastic, metal, glass, porcelain) in your home and public places. It eliminates germs and odors on hard nonporous surfaces that you come in contact with everyday. Use **AXEN[®] Disinfectant Pump Spray**:

| | |
|-----------------------|------------------|
| In empty garbage cans | In diaper pails |
| In pet areas | In empty hampers |
| In sick rooms | On doorknobs |
| Under sinks | In bathrooms |

Fast/Easy/Effective: Use on finished surfaces in basements, closets, attics, laundry rooms, storage areas, vacation homes, boat interiors, shower stalls, and recycling bins. **AXEN[®] Disinfectant Pump Spray** is effective against Salmonella, Streptococcus, and Pseudomonas organisms.

Directions for Use

To disinfect, spray surface with **AXEN[®] Disinfectant** and let stand for 1 minute.

STORAGE AND DISPOSAL

| | |
|-----------------|---|
| Storage | Do not contaminate water, food or feed by storage or disposal. |
| Disposal | Do not reuse container. Rinse thoroughly before discarding in trash or recycling. |

DP BARCODE: D274407

CASE: 068118
SUBMISSION: S596157

DATA PACKAGE RECORD
BEAN SHEET

DATE: 04/25/01
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 189 RESB FOPA-OC-ME TOO
CHEMICALS: [REDACTED]

ID#: 072977-E AXEN

COMPANY: 072977 ETI H2O, INC.

PRODUCT MANAGER: 33 MARSHALL SWINDELL

703-308-6341 ROOM: CS1 6B

PM TEAM REVIEWER: MARTHA TERRY

703-308-6217 ROOM: CS1 6W10

RECEIVED DATE: 04/24/01 DUE OUT DATE: 08/22/01

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 274407 EXPEDITE: Y DATE SENT: 04/25/01 DATE RET.: / /

CHEMICAL: [REDACTED]

P TYPE: 001

CSF: N

LABEL: Y

ASSIGNED TO

DATE IN

DATE OUT

ADMIN DUE DATE: 07/29/01

DIV : AD

4/26/01

/ /

NEGOT DATE: 7/22/01

BRAN: PSB

4/24/01

/ /

PROJ DATE: / /

SECT: EET

4/26/01

/ /

REVR : White

5/3/01

/ /

CONTR:

/ /

/ /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the Efficacy Data (AOAC Use Dilution Test - MRID#450169) to support the new product for registration. This Data is for both registrations (72977-R and 72977-E). Also, included in this package is a copy of the company current proposed labels for both products and a copy of our "Minutes of Meeting which was held on 3/24/01 for both products. Thanks

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

| DP BC | BRANCH/SECTION | DATE OUT | DUE BACK | INS | CSF | LABEL |
|-------|----------------|----------|----------|-----|-----|-------|
|-------|----------------|----------|----------|-----|-----|-------|



Front Panel

Axen

EPA File Symbol 72977-E

revision May 2, 2001

AXEN[®]

Stabilized Ionic Silver
Hard Surface Disinfectant

Active Ingredient

Silver*..... 0.0012%

Citric Acid..... 4.8400%

Other Ingredients..... 95.1588%

Total 100.0000%

* Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA REG. No. 72977-E

EPA EST. No. XXXXX-X-XX

Manufactured by ETI H₂O,

Route 14, P. O. Box 1517

Lake City, FL 32024

Net Vol. 36 oz.

Back Panel
Axen
EPA File Symbol 72977-E
Revised May 2, 2001

AXEN® Disinfectant Pump Spray kills bacteria on environmental hard surfaces (painted, tile, plastic, metal, glass, porcelain) in your home and public places. It eliminates germs and odors on hard nonporous surfaces that you come in contact with everyday. Use **AXEN® Disinfectant Pump Spray**:

| | |
|-----------------------|------------------|
| In empty garbage cans | In diaper pails |
| In pet areas | In empty hampers |
| In sick rooms | On doorknobs |
| Under sinks | In bathrooms |

Fast/Easy/Effective: Use on finished surfaces in basements, closets, attics, laundry rooms, storage areas, vacation homes, boat interiors, shower stalls, and recycling bins. **AXEN® Disinfectant Pump Spray** is effective against Salmonella, Streptococcus, and Pseudomonas organisms.

Directions for Use

To disinfect, spray surface with **AXEN® Disinfectant** and let stand for 1 minute.

10 minutes

STORAGE AND DISPOSAL

| | |
|----------|---|
| Storage | Do not contaminate water, food or feed by storage or disposal. |
| Disposal | Do not reuse container. Rinse thoroughly before discarding in trash or recycling. |

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460



OFFICE OF PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES
Antimicrobials Division

May 30, 2001

MEMORANDUM:

Subject: Efficacy Review EPA Reg. No. 72977-R and 72977-E Axenohl and Axen
DP Barcode 274402 and 274407
Case No. 065218 and 652118

From: Nancy Whyte, Microbiologist *NW*
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

To: Marshall Swindell/Karen Leavy-Munk
Regulatory Management Branch I
Antimicrobials Division (7510C)

Thru: Emily Mitchell, M.S., Team Leader
Efficacy Evaluation Team
Product Science Branch
Antimicrobials Division (7510C)

Thru: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

Applicant: ETI H₂O
Route 15, PO Box 1517
Lake City FL 32024

| Formulation Label: | % by wt. |
|-----------------------------|-----------|
| <u>Active Ingredient(s)</u> | |
| Silver* | 0.0012% |
| Citric acid | 4.8400% |
| <u>Inert Ingredients</u> | 95.1588% |
| Total | 100.0000% |

*Electronically generated silver ions

I. Background:

The registrant has submitted two data packages for review of efficacy data to support

the registration of both a manufacturing-use product and an end-use product. The MUP (*Axenhol*) is used to formulate end-product disinfectants. The end-product (*Axen*) is distributed in a spray bottle for disinfection of hard, non-porous environmental surfaces in homes and institutions. The efficacy data was conducted on the MUP and submitted for review in one volume (MRID No. 450169-06).

II. Use Directions:

The directions for use printed on the label for *Axen* specify that surfaces to be disinfected should be sprayed with *Axen* and allowed to stand for one minute. There are no other directions for use on the end-product label. The MUP *Axenhol* label states that the product is to be diluted 1:199 with 4.76% aqueous citric acid for manufacturing use only.

III. Agency Standards for Proposed Change:

The Agency standard for hard surface, non-porous surface disinfectants is found in DIS-TSS-1 and -2 which specifies that the Association of Official Analytical Chemists (AOAC) Use-Dilution Test or Germicidal Spray Product Test be used in testing. This procedure requires that sixty carriers must be tested against each of both *Salmonella choleraesuis*, ATCC 10708 and *Staphylococcus aureus*, ATCC 6538, with each of three batches of the product, one of which must be at least 60 days old. If the product is to be used in health care facilities, the product must also be tested against *Pseudomonas aeruginosa*, ATCC 15442 (180 carriers per sample, a total of 40 carriers). The product must demonstrate that it kills all organisms on 59 out of each 60 carriers in order to support label claims for its effectiveness against these organisms. If additional disinfectant claims are made for other organisms, ten carriers for each specific organism must be tested with each of 2 samples, representing different batches (10 carriers per sample, a total of 20 carriers for each organism). Killing of all organisms on all carriers is required to demonstrate effectiveness.

IV. Summary of Submitted Study:

Efficacy testing to support registration requirements for this product were conducted by MicroBioTest, Inc. in Sterling, Va. in October 1999. A Good Laboratory Practices Statement was included with results of the efficacy study. According to the protocol included in the data submitted to the Agency, the testing procedure followed the AOAC *Official Methods of Analysis*, 15th edition, 1990 Use-Dilution Test. Three lots of *Axenhol*, Lot #AG-006, prepared in April 1999, Lot #8991, prepared in September 1999, and Lot #8995, prepared also in September 1999 were used as the testing material. The samples received from the registrant were prepared at the testing facility by adding one gram of the active test agent to 199 grams of 5%(w/w) citric acid solution to achieve a 200-gram final dilution. This dilution is equivalent to the ready-to-use end-product *Axen*. No organic soil load was added. Polished stainless steel penicylinders were used as carriers. Strains of *Salmonella choleraesuis*, ATCC 10708, *Staphylococcus aureus*, ATCC 6538, and *Pseudomonas aeruginosa*, ATCC 15442 from stock cultures were transferred daily for three consecutive days prior to use. Gram stains were used to verify growth. The inoculated cylinders were exposed to the product samples for 10 minutes at 20° +/- 1° C. The inoculum confirmation counts for each organism were as follows: *Sal. choleraesuis*, 1.1×10^8 , *S. aureus*, 4.2×10^8 , and *Pseudomonas aeruginosa*, 1.1×10^8 . Following incubation at 37 +/- 2° C for 48 hours, 59 of 60 carriers showed no growth when exposed to the product for 10 minutes, confirming the effectiveness of the product. All sterility

and viability control cultures met the criteria for a valid test.

V. Labeling:

1. This label is in need of a complete re-working.
2. The word "germs" must be removed from page two of the label.
3. The terms "tile" and "porcelain" must be preceded by the word "glazed"
4. In the section **Fast/Easy/Effective**: the specific items and locations in basements, attics, storage areas, vacation homes, and boat interiors must be listed. These areas are too general for label claims.
5. No efficacy testing has been done for any *Streptococcus* spp. The term "Streptococcus" must be removed.
6. Since no organic soil load was added in the efficacy testing procedure, a pre-cleaning step should be included in the directions especially in sick rooms, pet areas, and diaper pails.
7. The complete scientific names of the organisms tested for which label claims are made should be listed; i.e., *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*
8. The exposure time listed on the label for Axen is 1 minute. Efficacy testing was conducted with an exposure time of 10 minutes. The words "one minute" must be replaced with "ten minutes". Additional directions for completely wetting the surfaces, and any directions for removing any excess product must be added.

VI. Comments and Recommendations:

1. The manufacturing-use product Axenhol when tested at a 1:199 dilution (equivalent to the end-use product Axen) demonstrated effectiveness against *Salmonella choleraesuis*, ATCC 10708, *Staphylococcus aureus*, ATCC 6538, and *Pseudomonas aeruginosa*, ATCC 15442 exposed to the product for ten minutes.
2. The use of an organic soil load should be considered for future testing of other organisms that might be added to label claims.

Product Manager Please Note:

Please arrange a meeting with the registrant's consultant Mr. Jacoby to conduct a full label review of these products and give him instructions on how to format an acceptable label. He is aware that the attached label is woefully inadequate.

DP BARCODE: D274823

CASE: 068118
SUBMISSION: S597003

DATA PACKAGE RECORD
BEAN SHEET

DATE: 05/10/01
Page 1 of 1

FOPA

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 189 RESB FOPA-OC-ME TOO
CHEMICALS: [REDACTED]

ID#: 072977-E AXEN
COMPANY: 072977 ETI H2O, INC.
PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1 6B
PM TEAM REVIEWER: MARTHA TERRY 703-308-6217 ROOM: CS1 6W10
RECEIVED DATE: 05/08/01 DUE OUT DATE: 09/05/01

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 274823 EXPEDITE: N DATE SENT: 05/10/01 DATE RET.: / /
CHEMICAL: [REDACTED]
DP TYPE: 001

| | CSF: Y | LABEL: Y | |
|----------------|---------|----------|--------------------------|
| ASSIGNED TO | DATE IN | DATE OUT | ADMIN DUE DATE: 08/13/01 |
| DIV : AD | 5/10/01 | / / | NEGOT DATE: 8/5/01 |
| BRAN: PSB | 5/10/01 | / / | PROJ DATE: 7/21/01 |
| SECT: CTT | 5/10/01 | / / | |
| REVR : Wallace | 5/14/01 | / / | |
| CONTR: | / / | / / | |

* * * DATA REVIEW INSTRUCTIONS * * *

Attention: Wallace Powell
PLEASE REVIEW: This package contains a data waiver request for an acute inhalation study, NEW LABEL and a revised CSF, along with other documentations to support this new chemical. Thanks

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

| DP BC | BRANCH/SECTION | DATE OUT | DUE BACK | INS | CSF | LABEL |
|--------|----------------|----------|----------|-----|-----|-------|
| 274821 | PSB/CTT | 05/10/01 | 08/13/01 | Y | Y | Y |

77



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

June 21, 2001

MEMORANDUM

Subject: D274823

AXEN, EPA File Symbol 72977-E

From: Wallace Powell, Biologist
Product Science Branch
Antimicrobials Division (7510C)

Wallace Powell
06-21-01

Thru: Karen P. Hicks, Team Leader
Chemistry/Toxicology Team
Product Science Branch
Antimicrobials Division (7510C)

Karen P. Hicks
6/21/01

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

To: Marshall Swindell, Product Manager, Team 33
Martha Terry, Team Reviewer, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510C)

BACKGROUND

The applicant, ETI H₂O, Inc. (as represented by an agent), has submitted a package for registration of the subject product, AXEN. The package includes requests for waiver of acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, skin irritation, and skin sensitization data. The acute inhalation waiver requests is accompanied by a submitted rationale. The other four waiver requests are accompanied by citation of the agency's Citric Acid Reregistration Eligibility Decision (RED) document. For the eye irritation requirement, a study on AXEN (MRID 450165-01) was previously accepted.

AXEN is labeled as a hard surface disinfectant pump spray product containing the active ingredients silver (as ions, 0.0012% of the formulation by weight) and citric acid (4.84% of the formulation by weight).

RECOMMENDATION

Eye irritation

Eye irritation has been assigned to Category IV, based on MRID 450165-01 (refer to 05/08/00 Product Science Branch memorandum, Data Package D263138).

Acute oral and acute dermal toxicity, skin irritation

The applicant has cited the Citric Acid RED to support these data requirements. Based on the product formulation, the acute toxicity and skin irritation of AXEN is expected to be similar to what the citric acid component would be, at its concentration of 4.8%. This is far less than the concentration which the Citric Acid RED characterizes as mild with respect to systemic acute toxicity. Therefore, Product Science Branch (PSB) recommends Category IV for acute oral and acute dermal toxicity.

The RED characterizes technical grade citric acid as a moderate skin irritant. However, because 4.8% is far less concentration than technical grade and because the submitted eye irritation study for AXEN indicates eye irritation Category IV, skin irritation Category IV is also expected.

As further support for Category IV, note that in a 03/15/01 agency letter, the applicant's other product Axehnlol (EPA File Symbol 72977-R) was assigned Toxicity Category IV for acute oral and acute dermal toxicity and for skin irritation, based on submitted studies (refer to 02/03/01 PSB memorandum, Data Package D270802). AXEN has similar components but is far less concentrated than Axehnlol.

Skin sensitization

PSB recommends classification of AXEN as Non-sensitizer. The applicant has cited the Citric Acid RED document, which of course indicates no concern regarding skin sensitization for that chemical. The small set of additional chemicals in AXEN are not expected to add significant skin sensitization potential at the concentrations present.

Acute inhalation toxicity

The request for waiver of acute inhalation toxicity data is acceptable, for the following reasons.

- Based on the product formulation, the acute toxicity of AXEN is expected to be similar to what the citric acid component would be, at its concentration of 4.8%. This is far less than the concentration which the Citric Acid RED characterizes as mild with respect to systemic acute toxicity.
- Based on the Category IV data mentioned above for Axehnlol (EPA File Symbol 72977-R), which is more concentrated than AXEN, the acute toxicity of AXEN is expected to be quite mild.

- Although some inhalation exposure is expected, it is not expected to be particularly great, as the applicant points out. (No aerosol application appears on the label, and the product is not expected to be highly volatile.) This of course is not sufficient waiver justification in itself, but it is somewhat meaningful in association with the above comments.

Summary

An acute toxicity regulatory status for the subject product is summarized in the following table.

| Data Requirement | Means of Support | Status/ Acute Tox. Category |
|-----------------------|---|-----------------------------|
| Acute Oral Toxicity | Waiver request and RED citation | Waived/ IV |
| Acute Dermal Toxicity | Waiver request and RED citation | Waived/ IV |
| Acute Inhalation Tox. | Waiver request and RED citation | Waived/ IV |
| Eye Irritation | Previously submitted study,
MRID 450165-01 | Acceptable/ IV |
| Skin Irritation | Waiver request and RED citation | Waived/ IV |
| Skin Sensitization | Waiver request and RED citation | Waived/ Non-sensitizer |

Product Labeling

The human-hazard precautionary statements on the proposed product label identified as "revision May 2, 2001," are acceptable. (They are "KEEP OUT OF REACH OF CHILDREN" and "CAUTION".) No first aid statements are required.

DP BARCODE: D274821

CASE: 068118
SUBMISSION: S597003

DATA PACKAGE RECORD
BEAN SHEET

DATE: 05/10/01
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 189 RESB FOPA-OC-ME TOO
CHEMICALS:

ID#: 072977-E AXEN

COMPANY: 072977 ETI H2O, INC.

PRODUCT MANAGER: 33 MARSHALL SWINDELL

703-308-6341 ROOM: CS1 6B

PM TEAM REVIEWER: MARTHA TERRY

703-308-6217 ROOM: CS1 6W10

RECEIVED DATE: 05/08/01 DUE OUT DATE: 09/05/01

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 274821 EXPEDITE: N DATE SENT: 05/10/01 DATE RET.: / /

CHEMICAL:

DP TYPE: 001

CSF: Y

LABEL: Y

ASSIGNED TO

DATE IN

DATE OUT

ADMIN DUE DATE: 08/13/01

DIV : AD

5/10/01

/ /

NEGOT DATE: 8/5/01

BRAN: PSB

5/10/01

/ /

PROJ DATE: 7/21/01

SECT: CTT

5/10/01

/ /

REVR: *Nancy*

5/18/01

/ /

CONTR:

* * * DATA REVIEW INSTRUCTIONS * * *

Attention: Nancy Whyte

Please review the revised CSF, NEW LABEL, and MSDS along with other documentations to support the new chemical for registration. This information was requested by the Agency per meeting with the company, ETI H2O, on 4/24/01.

PLEASE NOTE: Nancy has the original package for this new chemical. Please give directly to her. Thanks

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

| DP BC | BRANCH/SECTION | DATE OUT | DUE BACK | INS | CSF | LABEL |
|-------|----------------|----------|----------|-----|-----|-------|
|-------|----------------|----------|----------|-----|-----|-------|



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of **Axen**

DP Barcode: **D274821** Reg. No. or File Symbol: **72977-E**
Manufacturing-use [**X**] End-use Product []

Active Ingredient Composition:

Silver*.....**0.0012%**

Citric acid.....**4.8400%**

* electrolytically generated silver ions

TO: Marshall Swindell PM 33

FROM: Alex Traska, Chemist
 Product Science Branch, CT Team
 Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader
 Product Science Branch
 Antimicrobials Division (7510C)

THRU: Michele E. Wingfield, Chief
 Product Science Branch
 Antimicrobials Division (7510 C)

BACKGROUND:

This re-submission, in support of the new product registration of **Axen** (EPA Reg. No. 72977-E) an end-use hard surface disinfectant was submitted by regulatory consultant Henry Jacoby, on behalf of the registrant, ETI H2O, Inc.

This re-submission, in support of the **Axen** registration, which is in response

to the March 26, 2001 Agency letter. In this letter a number of critical deficiencies were noted. This re-submission addresses the corrections which were requested in the Agency letter.

The following documents were submitted and examined in the chemistry review of this submission: agent's cover letter dated May 2, 2001, application covering this re-submission dated 5/2/01, revised Basic Formulation CSF for **Axen** dated 5/2/01, Certification with Respect to Citation of Data dated 5/2/01 which opted for the selective method of support, Data Matrix dated 5/2/01 for silver and citric acid, technical information covering citric acid and revised product label dated May 2, 2001.

FINDINGS:

1. Citric acid or its synonym, anhydrous citric acid, is now identified as an active ingredient in the CSF and on the label.
2. All other deficiencies noted in the prior review have been adequately addressed.
3. All other elements of the submission and CSF were acceptable.

RECOMMENDATIONS:

This re-submission, in support of the new product registration of **Axen**, is accepted.

06/15/01 AT

**HENRY JACOBY
REGULATORY CONSULTANT**

6709 ILEX COURT
NEW MARKET, MD 21774

PHONE: 301-865-9090
FAX: 301-865-4333

May 2, 2001

Environmental Protection Agency
Office of Pesticide Programs
Antimicrobial Division (H7507C)
Mr. Marshall Swindell
Room 308H Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Dear Marshall:

Re: RESUBMISSION OF APPLICATION FOR NEW REGISTRATION
Axen, EPA File Symbol 72977-E
ETI H₂O, INC

ETI H₂O, Inc. has appointed Henry Jacoby to represent it as its agent before the Office of Pesticide Programs of EPA. Please refer to the enclosed letter of appointment signed by Andrew Arata, President of ETI H₂O, Inc.

Please forward all correspondence relative to ETI H₂O, Inc to Henry Jacoby, 6709 Ilex Court, New Market, MD 21774.

This letter is in response to the Agency's letter of March 26, 2001 which delineated several deficiencies with the application.

Regarding the inhalation toxicity test, ETI H₂O, Inc is requesting a waiver from the requirement. See the attachment for further information.

I believe the confusion over the efficacy study to which you refer to in your letter of November 29, 2000 has been cleared up as a result of our meeting with your staff. It is my understanding the AOAC use dilution study (MRID No. 45016906) has been put into review.

Enclosed is a data matrix for silver and citric acid. The method of support for this application is the "Selective Method." The

Office of Pesticide Programs
U. S. Environmental Protection Agency
Attn: Marshall Swindell, PM 33
RESUBMISSION FOR NEW REGISTRATION
Axen
EPA FILE SYMBOL 72977-E

05/02/01

Page 2

application relies on the data references given in the Agency's Reregistration Eligibility Document (RED) for silver and citric acid. These documents relied on information in the public literature to support the reregistration of silver and citric acid. Since the proposed uses of AXEN is not substantially different from the currently registered uses, the waivers given in the RED should apply to the toxicity and exposure data requirements needed to support this application. The only exception to this is the two avian studies, which were submitted by Mason Chemical Company. ETI H₂O has sent a offer to pay letter to Mason Chemical Company.

CONTENT OF SUBMISSION

1. EPA Form 8570-1 (EPA File Symbol 72977-E)
2. EPA Form 8570-4 (two original copies)
3. EPA Form 8570-34 (Selective method, using cited data)
4. EPA Form 8570 (agency internal copy and public file copy) for silver, citric acid and citric acid and silver.
5. Request for a Waiver from Acute Inhalation Testing with supporting report.
6. Five (5) copies of draft labeling.
7. Agent appointment letter of April 27, 2001.

Sincerely yours,


Henry Jacoby



United States
Environmental Protection Agency
Washington DC 20460

☒ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|--|--|--|
| 1. Company/Product Number

72977-E | 2. EPA Product Manager

Marshall Swindell | 3. Proposed Classification

<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name)

Axen | PM#

33 | |
| 5. Name and Address of Applicant (Include ZIP Code)
ETI H2O
Route 14, Box 1517
Lake City, FL 32034

<input type="checkbox"/> Check if this is a new address | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____ | |

Section - II

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input checked="" type="checkbox"/> Resubmission in response to Agency letter dated <u>3/26/01</u> | <input type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Section - III

| | | | | | |
|--|--|---|-------------------|--|--|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging
<input type="checkbox"/> Yes
<input checked="" type="checkbox"/> No | Unit Packaging
<input checked="" type="checkbox"/> Yes
<input type="checkbox"/> No | Water Soluble Packaging
<input checked="" type="checkbox"/> Yes
<input type="checkbox"/> No | | <input checked="" type="checkbox"/> Metal | |
| * Certification must be submitted | | | | <input type="checkbox"/> Plastic | |
| If "Yes" Unit Packaging wgt. | No. per container | If "Yes" Package wgt. | No. per container | <input type="checkbox"/> Glass | |
| | | | | <input type="checkbox"/> Paper | |
| | | | | <input type="checkbox"/> Other (Specify) _____ | |
| 3. Location of Net Contents Information
<input checked="" type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container | | 5. Location of Label Directions
<input checked="" type="checkbox"/> On Label
<input type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product
<input checked="" type="checkbox"/> Lithograph
<input type="checkbox"/> Paper glued
<input type="checkbox"/> Stenciled | | <input type="checkbox"/> Other _____ | | | |

Section - IV

| | | | | | |
|---|--|--------------------------------|--|---|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | | | |
| Name

Henry Jacoby | | Title

Agent | | Telephone No. (Include Area Code)

(301) 865-9090 | |
| Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete.
I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | | | 6. Date Application Received

(Stamped) |
| Signature

 | | 3. Title

Agent, ETI H2O | | | |
| Typed Name

Henry Jacoby, Agent | | 5. Date

5/2/01 | | | |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
 401 M Street, S.W.
 WASHINGTON, D.C. 20460

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Certification with Respect to Citation of Data

| | |
|---|--|
| Applicant's/Registrant's Name, Address, and Telephone Number
ETI H2O, Route 14, Box 1517, Lake City, FL 32054 | EPA Registration Number/File Symbol
72977-E |
| Active Ingredient(s) and/or representative test compound(s)
Silver & Citric Acid | Date |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
Manufacturing Use Product | Product Name
Axen |

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

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SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirement.)

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

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| | | |
|----------------------------------|----------------|--|
| Signature
<i>Henry Jacoby</i> | Date
5/2/01 | Typed or Printed Name and Title
Henry Jacoby, Agent |
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51

Front Panel
Axen
EPA File Symbol 72977-E
revision May 2, 2001

AXEN®

Stabilized Ionic Silver
Hard Surface Disinfectant

Active Ingredient

Silver*..... 0.0012%

Citric Acid..... 4.8400%

Other Ingredients..... 95.1588%

Total 100.0000%

* Electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN

CAUTION

EPA REG. No. 72977-E

EPA EST. No. xxxxx-x-xx

Manufactured by ETI H₂O,

Route 14, P. O. Box 1517

Lake City, FL 32024

Net Vol. 36 oz.

8/1

Back Panel
Axen
EPA File Symbol 72977-E
Revised May 2, 2001

AXEN® Disinfectant Pump Spray kills bacteria on environmental hard surfaces (painted, tile, plastic, metal, glass, porcelain) in your home and public places. It eliminates germs and odors on hard nonporous surfaces that you come in contact with everyday. Use **AXEN® Disinfectant Pump Spray**:

| | |
|-----------------------|------------------|
| In empty garbage cans | In diaper pails |
| In pet areas | In empty hampers |
| In sick rooms | On doorknobs |
| Under sinks | In bathrooms |

Fast/Easy/Effective: Use on finished surfaces in basements, closets, attics, laundry rooms, storage areas, vacation homes, boat interiors, shower stalls, and recycling bins. **AXEN® Disinfectant Pump Spray** is effective against Salmonella, Streptococcus, and Pseudomonas organisms.

Directions for Use

To disinfect, spray surface with **AXEN® Disinfectant** and let stand for 1 minute.

STORAGE AND DISPOSAL

| | |
|----------|---|
| Storage | Do not contaminate water, food or feed by storage or disposal. |
| Disposal | Do not reuse container. Rinse thoroughly before discarding in trash or recycling. |



Disinfection With Environmental Perspective

Rt. 14 Box 1517, Lake City, FL 32024
V. 904-755-0389 FAX: 904-755-8642
E-Mail: microbio@alltel.net

Date: 4-27-2001

From: Andrew Arata

To: Henry Jacoby

Subject: Authorized Agent For ETI H2O, Inc. EPA Matters

To Whom it may concern:

ETIH2O, Inc. authorizes Henry Jacoby, Regulatory Consultant, 6709 Ilex Court, New Market, MD 21774, to act on behalf of ETI H2O, Inc., on all matters relating to regulatory actions and registrations before the US Environmental Protection Agency.

Sincerely:

Andrew B. Arata
President, ETIH2O, Inc.

A handwritten signature in black ink, appearing to read "Andrew B. Arata". The signature is fluid and cursive, with the first name "Andrew" being more prominent and the last name "Arata" following in a similar style.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved UMD No 2070-0060

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DATA MATRIX

| | | | | | |
|---|--|------------------------------------|---------------------------------------|-------------|----------------|
| Date
April 23, 2001 | | EPA Reg No./File Symbol
72977-E | | Page 1 of 1 | |
| Applicant's/Registrant's Name & Address
ETI H2O, Route 14, Box 1517, Lake City, FL 32054 | | | Product
Axen | | |
| Ingredient Silver & Citric Acid | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| SERIES 830 | Product Identity & Composition | 45016502 | ETI H2O | own | Accepted |
| OPPTS 830.6317 | Storage Stability | 45182002 | ETI H2O | own | Accepted |
| OPPTS 870.2400 | Acute Eye Irritation | 46046501 | ETI H2O | own | Accepted |
| OPP 158.640 | Product Performance (AOAC use dilution test) | 45016906 | ETI H2O | own | Accepted |
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| Signature
<i>Henry Jacoby</i> | | | Name and Title
Henry Jacoby, Agent | | Date
5/2/01 |



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April 23, 2001 | | EPA Reg No./File Symbol
72977-E | | Page 1 of 1 | |
| Applicant's/Registrant's Name & Address
ETI H2O, Route 14, Box 1517, Lake City, FL 32054 | | | Product
Axe | | |
| Ingredient Silver & Citric Acid | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| | | | ETI H2O | own | Accepted |
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| Signature
<i>Henry Jacoby</i> | | | Name and Title
Henry Jacoby, Agent | | Date
5/2/01 |



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401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

| | | | | |
|--|----------------|-------------------------|---------|-------------|
| Date | April 16, 2001 | EPA Reg No./File Symbol | 72977-E | Page 1 of 2 |
| Applicant's/Registrant's Name & Address | | Product | | |
| ETI H2O, Route 14, Box 1517, Lake City, FL 32054 | | Axen | | |

Ingredient Citric Acid

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|---|-------------|-------------------------------------|--------|------|
| OPPTS Series 830 | Group B - Physical/Chemical Properties | N/A | Reregistration Eligibility Document | PL | 1 |
| OPPTS 870.1100 | Acute Oral Toxicity | N/A | " | " | 1 |
| OPPTS 870.1200 | Acute Dermal Toxicity | N/A | " | " | 1 |
| OPPTS 870.1300 | Acute Inhalation Toxicity | N/A | " | " | 1 |
| OPPTS 870.2400 | Acute Eye Irritation | N/A | " | " | 1 |
| OPPTS 870.2500 | Acute Dermal Irritation | N/A | " | " | 1 |
| OPPTS 870.2600 | Skin Sensitization Test | N/A | " | " | 1 |
| OPPTS 850.2100 | Avian Acute Oral Toxicity Test | N/A | " | " | 1 |
| OPPTS 850.2200 | Avian Dietary Toxicity Test | N/A | " | " | 1 |
| OPPTS 850.1075 | Fish Acute Toxicity Test, freshwater and marine | N/A | " | " | 1 |
| OPPTS 850.1010 | Aquatic Invertebrate Acute Toxicity Test, Daphnia | N/A | " | " | 1 |
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|-----------|--|----------------|----------------------------------|------|---------|
| Signature | | Name and Title | Agent
Andrew Arata, President | Date | 5/02/01 |
|-----------|--|----------------|----------------------------------|------|---------|

DATA MATRIX

1. Reregistration Eligibility Document - Citric Acid, Prevention, Pesticides And Toxic Substances, EPA-738-F-92-017, June 1992, Page 5.

"In considering citric acid for reregistration eligibility, the Agency believes it is an active ingredient that should be considered for this broad waiver of the generic data requirements. The considerations that lead the Agency to this conclusion are as follows:

The U. S. FDA lists citric acid as a multiple purpose "generally recognized as safe" (GRAS) food substance (21 CFR part 182). Citric acid is also approved by the Joint FAO/WHO Expert Committee on Food Additives for use in foods without limitation.

There is no indication in the available information on citric acid as provided by the registrant that suggests that citric acid would constitute a hazard to the public or to the environment. Citric acid is widely distributed in plants and animals and occurs naturally in foods in substantial quantities. It is a well-known intermediate in carbohydrate metabolism and ingested citrate is considered to be completely metabolized.

Citric acid from living organisms is found naturally in soil and water. Citrates leached from rotting vegetation and produced by microorganisms have been detected at low levels through the ecosystem. Citric acid degrades readily when in contact with a variety of microorganisms that are found in soil, natural waters or sewage treatment systems. There is negligible human and environmental exposure to citric acid as a pesticide as a result of current registered use patterns, e.g., it has a low use rate and frequency of application.

No reports or adverse effects have been submitted to the Agency for this active ingredient. Citric acid, is, however, a severe eye irritant and moderate skin irritant, so appropriate label precautions are necessary. There is no indication of any other significant adverse effects from citric acid to humans or the environment associated with its use as a pesticide.

DATA MATRIX

Based on these factors the Agency does not believe generic data beyond those data required to satisfy basic product identity and chemistry questions ... are necessary to determine if the current registered uses of this active ingredient pose unreasonable risks to humans or the environment. Therefore, the Agency waived all generic data requirements except the basic product identity and chemistry data. The Agency believes that, based on the above factors, the registered uses of citric acid do not pose unreasonable risks to humans or the environment."

The present application does not result in an use that is substantially different from those already registered. Therefore the Agency's rationale and waiver is applicable. No additional data are required.



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|--|----------------|-------------------------|---------|-------------|
| Date | April 16, 2001 | EPA Reg No./File Symbol | 72977-E | Page 1 of 2 |
| Applicant's/Registrant's Name & Address | | Product | | |
| ETI H2O, Route 14, Box 1517, Lake City, FL 32054 | | Axen | | |

| Ingredient Silver | | | | | |
|----------------------------|---|-------------|-------------------------------------|--------|------|
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| OPPTS Series 830 | Group B - Physical/Chemical Properties | N/A | Reregistration Eligibility Document | PL | 1 |
| OPPTS 870.1100 | Acute Oral Toxicity | N/A | " | " | 1 |
| OPPTS 870.1200 | Acute Dermal Toxicity | N/A | " | " | 1 |
| OPPTS 870.1300 | Acute Inhalation Toxicity | N/A | " | " | 1 |
| OPPTS 870.2400 | Acute Eye Irritation | N/A | " | " | 1 |
| OPPTS 870.2500 | Acute Dermal Irritation | N/A | " | " | 1 |
| OPPTS 870.2600 | Skin Sensitization Test | N/A | " | " | 1 |
| OPPTS 850.2100 | Avian Acute Oral Toxicity Test | N/A | Mason Chemical Company | PAY | |
| OPPTS 850.2200 | Avian Dietary Toxicity Test | N/A | Mason Chemical Company | PAY | |
| OPPTS 850.1075 | Fish Acute Toxicity Test, freshwater and marine | N/A | Reregistration Eligibility Document | PL | 1 |
| OPPTS 850.1010 | Aquatic Invertebrate Acute Toxicity Test, Daphnia | N/A | " | " | 1 |
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Signature

Henry Jacoby

Name and Title

Henry Jacoby, Agent

Date

3/2/01

DATA MATRIX

1. Reregistration Eligibility Document and Fact Sheet-Silver, Prevention, Pesticides And Toxic Substances, EPA-xxx-x-xx-xxx, ???month??? 1992. Page 2 of the Fact Sheet.

"Most usually-required toxicity and exposure studies have been waived for silver since adequate published information is available." See References on pages 34 through 37 of the RED document on silver.

2. My company is will to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), when the Agency formally requests such data from companies with currently registered products containing an unregistered source of silver. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing the data, if necessary.

REQUEST FOR A WAIVER FROM THE REQUIREMENT OF

OPPTS 870.1300

ACUTE INHALATION TOXICITY TESTING

ETI H₂O requests a waiver from the requirement of submitting the Acute Inhalation Toxicity Testing (OPPTS 870.1300) for their product **AXEN**[®]. This waiver is based on a number of factors: formulation, low toxicity, packaging, and aerodynamic properties.

The formulation of **AXEN**[®] is predominantly [REDACTED]. The remaining ingredients are citric acid, [REDACTED] and ionic silver. This formulation tested out as category IV for acute oral, acute dermal, eye and skin irritation toxicity tests and negative as a skin sensitizer. [REDACTED] and ionic silver are present at [REDACTED] of the formulation. The only chemical, beside [REDACTED] present at a significant level is citric acid (~5% w/w). Information from toxnet¹ on the toxic effects of citric acid states "A moderately strong acid with irritant and allergenic properties. It is generally considered harmless except in large ingestions or chronic exposure." This is not the case with **AXEN**[®]. None of the of components present in the formulation are at a level to result in a significant toxic response. At 100% exposure of the product to rats in the inhalation study the only likely effect to be observed might be mild tissue irritation as a result of the acidic effects since the formulation has a pH of 1.79.

The product will be packaged as a ready-to-use spray. The spray utilized is a trigger spray similar to those employed with many of the household cleaning products. The particular trigger spray being used with **AXEN**[®] will generate a stream of product at ~1-2 mL per squeeze. The nozzle will be non-adjustable.

The application of this product using the trigger spray with its direct stream is not likely to produce a significant amount of aerosol particles. And of the aerosol particle produced, little or none of them will be less than 100µ in size. Since the product is predominantly composed of [REDACTED] with no volatile components, its density is very close to that of [REDACTED]. Because of the low amounts of components, other than [REDACTED] and their relatively low volatility, any aerosol particles produced are likely to behave aerodynamically similar to that of [REDACTED].

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In summary, this waiver request is based on the following facts:

1. None of the components in the formulation are present at a concentrate sufficiently high to result in a metabolic toxic effect when inhaled. The pH of the formulation is in the range that might result in mild irritation to the mucous membranes.
2. There is little or no reason to expect a large percentage of respirable particles being produced by the trigger spray application of this product.
3. Carrying out an acute inhalation toxicity test with this product would not significantly alter the present knowledge base or effect a change in the precautionary labeling, since a concentration of citric acid many time higher than present in AXEN[®] would only be moderately irritating at worst.

¹ Hazardous Substances Data Bank Report, page 3 of 21, Clinical Effects, 0.2.1.1, page 3 of 21, <http://toxnet.nlm.nih.gov>



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|---|--|
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ETI H2O, Route 14, Box 1517, Lake City, FL 32054 | EPA Registration Number/File Symbol
72977-E |
| Active ingredient(s) and/or representative test compound(s)
Silver & Citric Acid | Date |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
Manufacturing Use Product | Product Name
Axen |

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I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

Date

5/2/01

Typed or Printed Name and Title

Henry Jacoby, Agent



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401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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| Date | | April 16, 2001 | | EPA Reg No./File Symbol | 72977-E | Page 1 of 3 |
| Applicant's/Registrant's Name & Address | | | | Product | | |
| ETI H2O, Route 14, Box 1517, Lake City, FL 32054 | | | | Axon | | |
| Ingredient Citric Acid | | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note | |
| | | | Reregistration Eligibility Document | PL | I | |
| | | | Reregistration Eligibility Document | PL | I | |
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| | | | Reregistration Eligibility Document | PL | I | |
| Signature | | | Name and Title | | Date | |
| | | | Andrew Arnold, President | | 5/02/01 | |

DATA MATRIX

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There is no indication in the available information on citric acid as provided by the registrant that suggests that citric acid would constitute a hazard to the public or to the environment. Citric acid is widely distributed in plants and animals and occurs naturally in foods in substantial quantities. It is a well-known intermediate in carbohydrate metabolism and ingested citrate is considered to be completely metabolized.

Citric acid from living organisms is found naturally in soil and water. Citrates leached from rotting vegetation and produced by microorganisms have been detected at low levels through the ecosystem. Citric acid degrades readily when in contact with a variety of microorganisms that are found in soil, natural waters or sewage treatment systems. There is negligible human and environmental exposure to citric acid as a pesticide as a result of current registered use patterns, e.g., it has a low use rate and frequency of application.

No reports or adverse effects have been submitted to the Agency for this active ingredient. Citric acid, is, however, a severe eye irritant and moderate skin irritant, so appropriate label precautions are necessary. There is no indication of any other significant adverse effects from citric acid to humans or the environment associated with its use as a pesticide.

DATA MATRIX

Based on these factors the Agency does not believe generic data beyond those data required to satisfy basic product identity and chemistry questions ... are necessary to determine if the current registered uses of this active ingredient pose unreasonable risks to humans or the environment. Therefore, the Agency waived all generic data requirements except the basic product identity and chemistry data. The Agency believes that, based on the above factors, the registered uses of citric acid do not pose unreasonable risks to humans or the environment."

The present application does not result in an use that is substantially different from those already registered. Therefore the Agency's rationale and waiver is applicable. No additional data are required.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

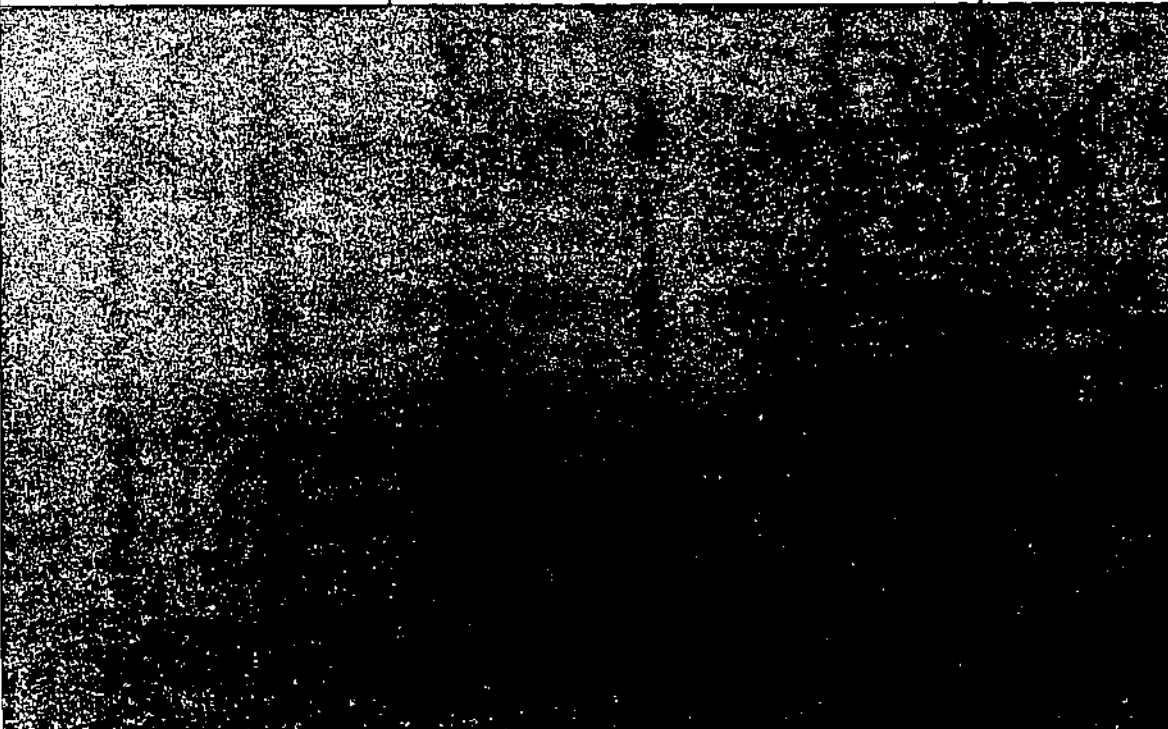
Form Approved CMB No. 2070-0060

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DATA MATRIX

| | | | | |
|--|----------------|-------------------------|---------|-------------|
| Date | April 23, 2001 | EPA Reg No./File Symbol | 72977-E | Page 1 of 2 |
| Applicant's/Registrant's Name & Address | | Product | | |
| ETI H2O, Route 14, Box 1517, Lake City, FL 32054 | | Axen | | |

Ingredient Silver

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|--|----------------------|-------------|-------------------------------------|--------|------|
|  | | | Reregistration Eligibility Document | PL | I |
| | | | Reregistration Eligibility Document | PL | I |
| | | | Reregistration Eligibility Document | PL | I |
| | | | Reregistration Eligibility Document | PL | I |
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| | | | Reregistration Eligibility Document | PL | I |
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| | | | Mason Chemical Company | PAY | |
| | | | Mason Chemical Company | PAY | |
| | | | Reregistration Eligibility Document | PL | I |
| | | | Reregistration Eligibility Document | PL | I |
| | | | | | |

Signature



Name and Title

Henry Jacoby, Agent

Date

5/2/01

DATA MATRIX

1. Reregistration Eligibility Document and Fact Sheet-Silver, Prevention, Pesticides And Toxic Substances, EPA-xxx-x-xx-xxx, ???month??? 1992. Page 2 of the Fact Sheet.

"Most usually-required toxicity and exposure studies have been waived for silver since adequate published information is available." See References on pages 34 through 37 of the RED document on silver.

2. My company is will to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), when the Agency formally requests such data from companies with currently registered products containing an unregistered source of silver. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing the data, if necessary.

Page ___ is not included in this copy.

Pages 107 through 108 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☒ The document is a duplicate of page(s) 98-99.
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

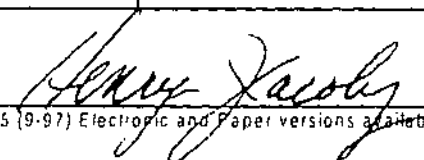
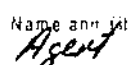
401 M Street, S.W.
WASHINGTON, D.C. 20460

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DATA MATRIX

| | | | | |
|--|----------------|-------------------------|---------|-------------|
| Date | April 16, 2001 | EPA Reg No./File Symbol | 72977-E | Page 1 of 2 |
| Applicant's/Registrant's Name & Address | | Product | | |
| ETI H2O, Route 14, Box 1517, Lake City, FL 32054 | | Axeit | | |

Ingredient Citric Acid

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|---|-------------|-------------------------------------|--|-----------------|
| OPPTS Series 830 | Group B - Physical/Chemical Properties | N/A | Reregistration Eligibility Document | PL | |
| OPPTS 870.1100 | Acute Oral Toxicity | N/A | " | " | |
| OPPTS 870.1200 | Acute Dermal Toxicity | N/A | " | " | |
| OPPTS 870.1300 | Acute Inhalation Toxicity | N/A | " | " | |
| OPPTS 870.2400 | Acute Eye Irritation | N/A | " | " | |
| OPPTS 870.2500 | Acute Dermal Irritation | N/A | " | " | |
| OPPTS 870.2600 | Skin Sensitization Test | N/A | " | " | |
| OPPTS 850.2100 | Avian Acute Oral Toxicity Test | N/A | " | " | |
| OPPTS 850.2200 | Avian Dietary Toxicity Test | N/A | " | " | |
| OPPTS 850.1075 | Fish Acute Toxicity Test, freshwater and marine | N/A | " | " | |
| OPPTS 850.1010 | Aquatic Invertebrate Acute Toxicity Test, Daphnia | N/A | " | " | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| Signature |  | | | Name and Title

Andrew Arata, President | Date
5/02/01 |

DATA MATRIX

1. Reregistration Eligibility Document - Citric Acid, Prevention, Pesticides And Toxic Substances, EPA-738-F-92-017, June 1992, Page 5.

"In considering citric acid for reregistration eligibility, the Agency believes it is an active ingredient that should be considered for this broad waiver of the generic data requirements. The considerations that lead the Agency to this conclusion are as follows:

The U. S. FDA lists citric acid as a multiple purpose "generally recognized as safe" (GRAS) food substance (21 CFR part 182). Citric acid is also approved by the Joint FAO/WHO Expert Committee on Food Additives for use in foods without limitation.

There is no indication in the available information on citric acid as provided by the registrant that suggests that citric acid would constitute a hazard to the public or to the environment. Citric acid is widely distributed in plants and animals and occurs naturally in foods in substantial quantities. It is a well-known intermediate in carbohydrate metabolism and ingested citrate is considered to be completely metabolized.

Citric acid from living organisms is found naturally in soil and water. Citrates leached from rotting vegetation and produced by microorganisms have been detected at low levels through the ecosystem. Citric acid degrades readily when in contact with a variety of microorganisms that are found in soil, natural waters or sewage treatment systems. There is negligible human and environmental exposure to citric acid as a pesticide as a result of current registered use patterns, e.g., it has a low use rate and frequency of application.

No reports or adverse effects have been submitted to the Agency for this active ingredient. Citric acid, is, however, a severe eye irritant and moderate skin irritant, so appropriate label precautions are necessary. There is no indication of any other significant adverse effects from citric acid to humans or the environment associated with its use as a pesticide.

DATA MATRIX

Based on these factors the Agency does not believe generic data beyond those data required to satisfy basic product identity and chemistry questions ... are necessary to determine if the current registered uses of this active ingredient pose unreasonable risks to humans or the environment. Therefore, the Agency waived all generic data requirements except the basic product identity and chemistry data. The Agency believes that, based on the above factors, the registered uses of citric acid do not pose unreasonable risks to humans or the environment."

The present application does not result in an use that is substantially different from those already registered. Therefore the Agency's rationale and waiver is applicable. No additional data are required.



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WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX

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|--|---|-------------------------|-------------------------------------|-------------|--------|
| Date | April 16, 2001 | EPA Reg No./File Symbol | 72977-E | Page 1 of 2 | |
| Applicant's/Registrant's Name & Address | | Product | | | |
| ETI H2O, Route 14, Box 1517, Lake City, FL 32054 | | Axen | | | |
| Ingredient Silver | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| OPPTS Series 830 | Group B - Physical/Chemical Properties | N/A | Reregistration Eligibility Document | PL | 1 |
| OPPTS 870.1100 | Acute Oral Toxicity | N/A | " | " | 1 |
| OPPTS 870.1200 | Acute Dermal Toxicity | N/A | " | " | 1 |
| OPPTS 870.1300 | Acute Inhalation Toxicity | N/A | " | " | 1 |
| OPPTS 870.2400 | Acute Eye Irritation | N/A | " | " | 1 |
| OPPTS 870.2500 | Acute Dermal Irritation | N/A | " | " | 1 |
| OPPTS 870.2600 | Skin Sensitization Test | N/A | " | " | 1 |
| OPPTS 850.2100 | Avian Acute Oral Toxicity Test | N/A | Mason Chemical Company | PAY | |
| OPPTS 850.2200 | Avian Dietary Toxicity Test | N/A | Mason Chemical Company | PAY | |
| OPPTS 850.1075 | Fish Acute Toxicity Test, freshwater and marine | N/A | Reregistration Eligibility Document | PL | 1 |
| OPPTS 850.1010 | Aquatic Invertebrate Acute Toxicity Test, Daphnia | N/A | " | " | 1 |
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| | | | | | |
| Signature | | | Name and Title | | Date |
| | | | Henry Jacoby, Agent | | 3/2/01 |

DATA MATRIX

1. Reregistration Eligibility Document and Fact Sheet-Silver, Prevention, Pesticides And Toxic Substances, EPA-xxx-x-xx-xxx, ???month??? 1992. Page 2 of the Fact Sheet.

"Most usually-required toxicity and exposure studies have been waived for silver since adequate published information is available." See References on pages 34 through 37 of the RED document on silver.

2. My company is will to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), when the Agency formally requests such data from companies with currently registered products containing an unregistered source of silver. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing the data, if necessary.




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WASHINGTON, D.C. 20460

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DATA MATRIX

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|--|--|------------------------------------|---------------------------------------|-------------|----------------|
| Date
April 23, 2001 | | ERA Reg No./File Symbol
72977-E | | Page 1 of 1 | |
| Applicant's/Registrant's Name & Address
ETI H2O, Route 14, Box 1517, Lake City, FL 32054 | | | Product
Asch | | |
| Ingredient Silver & Citric Acid | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| SERIES 830 | Product Identity & Composition | 45016502 | ETI H2O | own | Accepted |
| OPPTS 830.6317 | Storage Stability | 45182002 | ETI H2O | own | Accepted |
| OPPTS 870.2400 | Acute Eye Irritation | 46046501 | ETI H2O | own | Accepted |
| OPP 158.640 | Product Performance (AOAC use dilution test) | 45016906 | ETI H2O | own | Accepted |
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| Signature
 | | | Name and Title
Henry Jacoby, Agent | | Date
5/2/01 |

EPA Form 3570-35 (9-97) Electronic and Paper versions available. Submit only Paper version.

Agency Internal Use Copy

PREPARED BY HENRY JACOBY (301-865-9090)

SUBMISSION BAR CODE # 5596157 REVIEWER MT

CODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTS

FILE SYMBOL/REG NO. 72977-E PM 33 ACTION CODE 189

DESCRIPTOR Efficacy Data (AUA Use Dilution)

☐ CHILD RESISTANT PACKAGING: ☐ CERTIFICATION
☐ NON-RESIDENTIAL USE ONLY
☐ NOT APPLICABLE

REGISTRATION TYPE: ☐ CONDITIONAL ☐ UNCONDITIONAL

PROPOSED CLASSIFICATION: ☐ GENERAL ☐ RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

04 24 01

04 24 01

04 24 01

METHOD OF SUPPORT

FORMULATORS EXEMPTION

☐ CITE-ALL
☐ SELECTIVE
☐ NOT SUBMITTED
☐ NOT APPLICABLE
☐ INCORRECT/RESUB

☐ SUBMITTED
☐ NOT SUBMITTED
☐ NOT APPLICABLE
☐ INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA
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DATE
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DUE
DATE

DATE
RETURNED

CHEMISTRY

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STATUS

RESPONSE CODE

12

RESPONSE DATE

JUN 21 2001

Page ____ is not included in this copy.

Pages 116 through 123 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☒ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

SUBMISSION BAR CODE # 5590089REVIEWER MTCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 72977-E PM 33 ACTION CODE 159DESCRIPTOR Corrected CSF

[] CHILD RESISTANT PACKAGING: [] CERTIFICATION
[] NON-RESIDENTIAL USE ONLY
[] NOT APPLICABLE

REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL

PROPOSED CLASSIFICATION: [] GENERAL [] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

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| 12 | 14 | 00 |
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METHOD OF SUPPORT

FORMULATORS EXEMPTION

[] CITE-ALL
[] SELECTIVE
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

[] SUBMITTED
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

VIEW(S) REQUESTED

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DATEDATE
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TOXICOLOGY

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ENVIRON. FATE

FISH/WILDLIFE

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| D271464 | 12/27/00 | | |
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OTHER _____

STATUS _____

RESPONSE CODE 13RESPONSE DATE MAR 15 2001

ETI H₂O
Route 14, Box 1517
Lake City, FL 32054

Attention: John W. Kennedy, Agent

Subject: Axenohl

EPA File Symbol 72977-R
Application Dated December 8, 2000

Axen
EPA File Symbol 72977-E
Application Dated December 8, 2000

A review of your application package has determined that additional information will be required in order for us to continue processing your application. The following information must be corrected and submitted.

ACUTE TOXICOLOGY

The Agency has completed its review of the submitted acute toxicity studies and the comments are outlined below.

1. The acute oral toxicity, acute dermal toxicity, primary eye irritation and primary skin irritation studies are acceptable.
2. No acute inhalation toxicity study or waiver request for this study was included for this submission. In order to obtain Precautionary Labeling for this product, you must address the requirements for this study or submit justification as to why this study was not submitted.
3. The acute toxicity profile for EPA File Symbol 72977-R is listed below:

| | | |
|---------------------------|----------------|---------------|
| Acute oral toxicity | IV | Acceptable |
| Acute dermal toxicity | IV | Acceptable |
| Acute inhalation toxicity | | Not submitted |
| Primary eye irritation | III | Acceptable |
| Primary skin irritation | IV | Acceptable |
| Dermal sensitization | Non-sensitizer | Acceptable |

PRODUCT CHEMISTRY (AXENOHL)

The revised Basic Confidential Statement of Formula dated December 5, 2000 is incomplete and is not acceptable. The items listed below must be addressed on your CSF and submitted for our review.

FINDINGS:

1. The formula weight for the electrolytically generated silver in the Basic CSF must be increased from [REDACTED] in item 13a in order for the percentage weight to equal 0.2400% as given in item 13b and on the product label. Based on the 12/5/00 CSF, the percent by weight of silver is 0.2356%. It is suggested that the weight of the [REDACTED] in the formula be reduced by [REDACTED] to compensate for the increased use of silver.

2. The ingredient statement on product label for Axenohl must be revised to read as follows:

Active Ingredients:

| | |
|------------------------|-----------|
| *Silver..... | 0.2400% |
| Citric Acid..... | 20.6600% |
| Other Ingredients..... | 79.1000% |
| Total..... | 100.0000% |

*ionic silver generated electrolytically

Silver not silver citrate should be declared as an active ingredient. Additionally, due to the high concentration of citric acid or anhydrous citric acid present in this formulation, citric acid must be identified and declared as an active ingredient. At the levels utilized citric acid unquestionably provides antimicrobial activity. This assignment of citric acid as an active ingredient is required, despite of the fact that citric acid also functions as a stabilizer in this formulation.

3. The correct spelling of this product is Axenohl and not Axenhol as given in the application (EPA Form 8570-1).

4. Identify citric acid or its synonym, anhydrous citric acid, as an active ingredient in the CSF.

5. All other elements of the CSF were acceptable.

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PRODUCT CHEMISTRY (AXEN)

The revised Basic Confidential Statement of Formula dated December 5, 2000 is incomplete and is not acceptable. The items listed below must be addressed on your CSF and submitted for our review.

FINDINGS:

1. The ingredient statement on product label for Axenohl must be revised to read as follows:

Active Ingredients:

| | |
|------------------------|-----------|
| *Silver..... | 0.0012% |
| Citric Acid..... | 4.8387% |
| Other Ingredients..... | 95.1600% |
| Total..... | 100.0000% |

*ionic silver generated electrolytically

Due to the high concentration of citrate acid or anhydrous citric acid present in this formulation, citric acid must be identified and declared as an active ingredient. At these levels citric unquestionably provides antimicrobial activity. This assignment of citric acid as an active ingredient is required, despite of the fact that citric acid also functions as a stabilizer in this formulation.

2. The Basic CSF for Axen must be revised to incorporate the [REDACTED] increase in silver and [REDACTED] which was recommended for the 12/5/00 Axenol CSF in the chemistry review for Axenohl dated 3/9/01.

3. Identify citric acid or its synonym, anhydrous citric acid, as an active ingredient in the CSF.

4. All other elements, such as the certified limits, of the CSF were acceptable.

EFFICACY

The company has not complied with our request to correct the deficiencies as outlined in our letter dated November 29, 2000 under "SUMMARY OF INFORMATION REVIEWED AND FINDINGS/CONCLUSIONS."

127

DATA MATRIX

You are reminded that a new data compensation form listing silver as the active and a data matrix for the Technical Grade Silver Active Ingredient must be submitted for both the **Axen and Axenohl products**. You must also submit appropriate data compensation paperwork for the Citric Acid A.I. If you are using an unregistered source of active for the Citric Acid under the Selective Method of Support, you must submit a data matrix for the TGA Citric Acid.

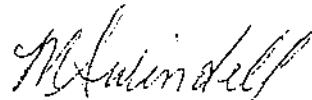
LABELING

The Agency reserves full labeling review at this time until the above deficiencies have been resolved. Just a reminder that additional information/data may be required to support your application after the corrected efficacy data have been submitted and reviewed.

This letter does not constitute registration and the product may not be lawfully marketed until all the required information has been submitted for review and found acceptable.

If you have any questions concerning this letter, please contact Martha Terry at (703) 308-6217.

Sincerely,



Marshall Swindell
Acting Product Manager 33
Regulatory Management Branch 1
Antimicrobial Division (7510C)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of **Axen**

DP Barcode: **D271464**

Reg. No. or File Symbol: **72977-E**

Manufacturing-use []

End-use Product [**X**]

Active Ingredient Composition:

* **Silver**0.0012%

* electrolytically generated silver ions

(as per undated product label which was post- dated 3/9/01 by the
reviewer of this submission)

TO: Marshall Swindell PM 33

FROM: Alex Traska, Chemist *AT 3/9/01*
Product Science Branch, CT Team
Antimicrobials Division (7510C)

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C) *KPH 3/9/01*

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510 C)

BACKGROUND:

This re- submission, in support of the new product registration of **Axen**
(EPA Reg. No. 72977-E) an end-use hard surface disinfectant, was submitted by
John W. Kennedy Consultants, Inc. on behalf of the registrant, ETI H2O, Inc.

The registrant is responding to the November 29, 2000 Agency letter in which deficiencies regarding **Axen** and its manufacturing-use counterpart were delineated. In this re-submission a revised CSF and additional information was provided for both **Axen** and **Axenohl**.

The following documents were submitted and examined in the chemistry review of this submission: agent's cover letter dated December 7, 2000, application covering this re-submission dated 12/8/00, revised Basic Formulation CSF for **Axen** dated 12/5/00, revised Basic Formulation CSF for **Axenohl** dated 12/5/00, Agency letter dated November 29, 2000 and undated product label which was post dated 3/9/01 by the reviewer.

FINDINGS:

1. The ingredient statement on product label for **Axen** must be revised to read as follows:

Active Ingredients:

| | |
|--------------------------|-----------|
| *Silver | 0.0012% |
| Citric Acid..... | 4.8387% |
| Other Ingredients: | 95.1601% |
| Total | 100.0000% |

*ionic silver generated electrolytically

Due to the high concentration of citric acid or anhydrous citric acid present in this formulation, citric acid must be identified and declared as an active ingredient. At these levels citric acid unquestionably provides antimicrobial activity. This assignment of citric acid as an active ingredient is required, despite of the fact that citric acid also functions as a stabilizer in this formulation.

2. The Basic CSF for **Axen** must be revised to incorporate the [REDACTED] increase in silver and [REDACTED] which was recommended for the 12/5/00 **Axenohl** CSF in the chemistry review for **Axenohl** dated 3/9/01.

3. Identify citric acid or its synonym, anhydrous citric acid, as an active ingredient in the CSF.

4. All other elements, such as the certified limits, of the CSF were acceptable.

130

RECOMMENDATIONS:

This re-submission, in support of the new product registration of Axen, is not accepted.

Issues discussed under Findings must be addressed by the registrant.

03/09/01 AT

DP BARCODE: D271464

CASE: 068118
SUBMISSION: S590089

DATA PACKAGE RECORD
BEAN SHEET

DATE: 12/27/00
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 189 RESE FQPA-OC-ME TOO
CHEMICALS:

ID#: 072977-E AXEN

COMPANY: 072977 ETI H2O, INC.

PRODUCT MANAGER: 33 MARSHALL SWINDELL 703-308-6341 ROOM: CS1 6B
PM TEAM REVIEWER: MARTHA TERRY 703-308-6217 ROOM: CS1 6W10
RECEIVED DATE: 12/12/00 DUE OUT DATE: 04/11/01

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 271464 EXPEDITE: N DATE SENT: 12/27/00 DATE RET.: / /
CHEMICAL:

TYPE: 001

CSF: Y

LABEL: Y

| ASSIGNED TO | DATE IN | DATE OUT | ADMIN DUE DATE: 04/01/01 |
|-------------|----------|----------|--------------------------|
| DIV : AD | 12/29/00 | / / | NEGOT DATE: 3/11/01 |
| BRAN: PSB | 12/29/00 | / / | PROJ DATE: 2/27/01 |
| SECT: CTT | 12/29/00 | / / | |
| REVR : alex | 1/2/01 | / / | |
| CONTR: | / / | / / | |

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the corrected CSF based on the Agency's comments in letter dated 11/29/00. Attached are copies of the previous CSF, label and current CSF.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

| DP BC | BRANCH/SECTION | DATE OUT | DUE BACK | INS | CSF | LABEL |
|-------|----------------|----------|----------|-----|-----|-------|
|-------|----------------|----------|----------|-----|-----|-------|

REVISIONS: 001, 002, 003, 004, 005, 006, 007, 008, 009, 010, 011, 012, 013, 014, 015, 016, 017, 018, 019, 020, 021, 022, 023, 024, 025, 026, 027, 028, 029, 030, 031, 032, 033, 034, 035, 036, 037, 038, 039, 040, 041, 042, 043, 044, 045, 046, 047, 048, 049, 050, 051, 052, 053, 054, 055, 056, 057, 058, 059, 060, 061, 062, 063, 064, 065, 066, 067, 068, 069, 070, 071, 072, 073, 074, 075, 076, 077, 078, 079, 080, 081, 082, 083, 084, 085, 086, 087, 088, 089, 090, 091, 092, 093, 094, 095, 096, 097, 098, 099, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 123, 124, 125, 126, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 138, 139, 140, 141, 142, 143, 144, 145, 146, 147, 148, 149, 150, 151, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 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1332, 1333, 1334, 1335, 1336, 1337, 1338, 1339, 1340, 1341, 1342, 1343, 1344, 1345, 1346, 1347, 1348, 1349, 1350, 1351, 1352, 1353, 1354, 1355, 1356, 1357, 1358, 1359, 1360, 1361, 1362, 1363, 1364, 1365, 1366, 1367, 1368, 1369, 1370, 1371, 1372, 1373, 1374, 1375, 1376, 1377, 1378, 1379, 1380, 1381, 1382, 1383, 1384, 1385, 1386, 1387, 1388, 1389, 1390, 1391, 1392, 1393, 1394, 1395, 1396, 1397, 1398, 1399, 1400, 1401, 1402, 1403, 1404, 1405, 1406, 1407, 1408, 1409, 1410, 1411, 1412, 1413, 1414, 1415, 1416, 1417, 1418, 1419, 1420, 1421, 1422, 1423, 1424, 1425, 1426, 1427, 1428, 1429, 1430, 1431, 1432, 1433, 1434, 1435, 1436, 1437, 1438, 1439, 1440, 1441, 1442, 1443, 1444, 1445, 1446, 1447, 1448, 1449, 1450, 1451, 1452, 1453, 1454, 1455, 1456, 1457, 1458, 1459, 1460, 1461, 1462, 1463, 1464, 1465, 1466, 1467, 1468, 1469, 1470, 1471, 1472, 1473, 1474, 1475, 1476, 1477, 1478, 1479, 1480, 1481, 1482, 1483, 1484, 1485, 1486, 1487, 1488, 1489, 1490, 1491, 1492, 1493, 1494, 1495, 1496, 1497, 1498, 1499, 1500, 1501, 1502, 1503, 1504, 1505, 1506, 1507, 1508, 1509, 1510, 1511, 1512, 1513, 1514, 1515, 1516, 1517, 1518, 1519, 1520, 1521, 1522, 1523, 1524, 1525, 1526, 1527, 1528, 1529, 1530, 1531, 1532, 1533, 1534, 1535, 1536, 1537, 1538, 1539, 1540, 1541, 1542, 1543, 1544, 1545, 1546, 1547, 1548, 1549, 1550, 1551, 1552, 1553, 1554, 1555, 1556, 1557, 1558, 1559, 1560, 1561, 1562, 1563, 1564, 1565, 1566, 1567, 1568, 1569, 1570, 1571, 1572, 1573, 1574, 1575, 1576, 1577, 1578, 1579, 1580, 1581, 1582, 1583, 1584, 1585, 1586, 1587, 1588, 1589, 1590, 1591, 1592, 1593, 1594, 1595, 1596, 1597, 1598, 1599, 1600, 1601, 1602, 1603, 1604, 1605, 1606, 1607, 1608, 1609, 1610, 1611, 1612, 1613, 1614, 1615, 1616, 1617, 1618, 1619, 1620, 1621, 1622, 1623, 1624, 1625, 1626, 1627, 1628, 1629, 1630, 1631, 1632, 1633, 1634, 1635, 1636, 1637, 1638, 1639, 1640, 1641, 1642, 1643, 1644, 1645, 1646, 1647, 1648, 1649, 1650, 1651, 1652, 1653, 1654, 1655, 1656, 1657, 1658, 1659, 1660, 1661, 1662, 1663, 1664, 1665, 1666, 1667, 1668, 1669, 1670, 1671, 1672, 1673, 1674, 1675, 1676, 1677, 1678, 1679, 1680, 1681, 1682, 1683, 1684, 1685, 1686, 1687, 1688, 1689, 1690, 1691, 1692, 1693, 1694, 1695, 1696, 1697, 1698, 1699, 1700, 1701, 1702, 1703, 1704, 1705, 1706, 1707, 1708, 1709, 1710, 1711, 1712, 1713, 1714, 1715, 1716, 1717, 1718, 1719, 1720, 1721, 1722, 1723, 1724, 1725, 1726, 1727, 1728, 1729, 1730, 1731, 1732, 1733, 1734, 1735, 1736, 1737, 1738, 1739, 1740, 1741, 1742, 1743, 1744, 1745, 1746, 1747, 1748, 1749, 1750, 1751, 1752, 1753, 1754, 1755, 1756, 1757, 1758, 1759, 1760, 1761, 1762, 1763, 1764, 1765, 1766, 1767, 1768, 1769, 1770, 1771, 1772, 1773, 1774, 1775, 1776, 1777, 1778, 1779, 1780, 1781, 1782, 1783, 1784, 1785, 1786, 1787, 1788, 1789, 1790, 1791, 1792, 1793, 1794, 1795, 1796, 1797, 1798, 1799, 1800, 1801, 1802, 1803, 1804, 1805, 1806, 1807, 1808, 1809, 1810, 1811, 1812, 1813, 1814, 1815, 1816, 1817, 1818, 1819, 1820, 1821, 1822, 1823, 1824, 1825, 1826, 1827, 1828, 1829, 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1996, 1997, 1998, 1999, 2000, 2



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|---|--|---|
| 1. Company/Product Number
EPA File Symbol 72977-E | 2. EPA Product Manager
Marshall Swindell | 3. Proposed Classification
<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| Company/Product (Name)
AXEN | PM#
33 | |
| Name and Address of Applicant (Include ZIP Code)
ETI H2O
Rt. 14, Box 1517
Lake City, FL 32054 | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(ii), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____ |
| <input type="checkbox"/> Check if this is a new address | | |

Section - II

| | |
|---|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input checked="" type="checkbox"/> Resubmission in response to Agency letter dated 11/29/00 | <input type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Corrections on CSE. Accounting for silver and explanation of anhydrous citric acid as a stabilizer explained. Starting materials to form Axen explained using Axenhol as a starting (Technical) product.

Section - III

| | | | |
|--|---|--|--|
| Material This Product Will Be Packaged In: | | | |
| Child-Resistant Packaging
<input type="checkbox"/> Yes
<input type="checkbox"/> No | Unit Packaging
<input type="checkbox"/> Yes
<input type="checkbox"/> No | Water Soluble Packaging
<input type="checkbox"/> Yes
<input type="checkbox"/> No | 2. Type of Container
<input type="checkbox"/> Metal
<input type="checkbox"/> Plastic
<input type="checkbox"/> Glass
<input type="checkbox"/> Paper
<input type="checkbox"/> Other (Specify) _____ |
| Certification must be submitted | If "Yes" Unit Packaging wgt. No. per container | If "Yes" Package wgt. No. per container | |
| Location of Net Contents Information
<input type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container | 5. Location of Label Directions
<input type="checkbox"/> On Label
<input type="checkbox"/> On Labeling accompanying product |
| Manner in Which Label is Affixed to Product
<input type="checkbox"/> Lithograph
<input type="checkbox"/> Paper glued
<input type="checkbox"/> Stenciled | | <input type="checkbox"/> Other _____ | |

Section - IV

| | | | |
|---|--|---|--|
| Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | |
| Name
John W. Kennedy | | Title
Consultant to ETI H2O
John W. Kennedy Consultants | Telephone No. (Include Area Code)
301-490-1600 |
| Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | 8. Date Application Received (Stamped) |
| Signature
John W. Kennedy | | 3. Title
John W. Kennedy | |
| Typed Name
John W. Kennedy | | 5. Date
12/8/00 | |

John W. Kennedy Consultants

13 "C" Street Suite G

Laurel, MD 20707

Phone: (301) 490-1600

Fax: (301) 490-5793

E-MAIL: John.Kennedy@consultants-jwk.com

December 7, 2000

Marshall Swindell
Product Manager 33
Antimicrobial Biogram Division (H7505C)
U. S. Environmental Protection Agency
Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202
Attn: Martha Terry

Subject: **Your letter of 11/29/00**
 Axen
 EPA File symbol No. 72977-E
 Axenohl
 EPA File symbol No. 72977-R

Dear Mr. Swindell,

JWKC Represents ETI-H2O. Dr. Ed Woolson has been the primary contact with ETI-H2O and we are responding to the subject letter.

Enclosed is the revised CSF for both Axen and Axenohl. The revision has taken into account the comments submitted in the chemistry review. The main function in the formulation is to keep the silver in solution. We request that citric acid be maintained as a stabilizer. At this time, ETIH2O wishes to drop the efficacy study for *Enterococcus faecium* since it is not necessary for the hard surface disinfectant registration.

We have not received the review for the hard surface disinfectant study run by

MicroBio Test, Inc. (Sterling VA.). Efficacy studies were submitted in November 1999. We understood during the meeting with you and Dr. Shamin on May 11, 2000 that the efficacy and toxicity studies had been reviewed and found acceptable. Perhaps we were wrong in our understanding. The MicroBio Test AOAC Use Dilution study was submitted on 11/99 and is identified as MRID 45016906. The summary of the data from that study indicates that **"Axenohl passes the AOAC Use Dilution Test when *S. aureus*, ATCC 6538; *S. choleraesuis*, ATCC 10708 and *P. aeruginosa*, ATCC 15442 are exposed to the test material for 10 minutes at 20±1 C. All of the sterility and viability control cultures met the resistance required to meet the criteria for a valid test. These conclusions are based on the observed data."**

In addition to the lack of review for the hard surface disinfectant study, we have not received reviews on the acute studies either. The EPA may have already reviewed the submitted in November 1999 for the technical, the same time as the MicroBio Test study. They are the acute oral (MRID 45016901), acute dermal (MRID 45016902), eye irritation (MRID 45016903), skin irritation (MRID 45016904) and dermal sensitization (MRID 45016905). Axenohl is non-toxic and Product Safety Labs listed it as a category 4 compound with slight eye irritation. The eye irritation for Axen (MRID 45016907) has been reviewed and found acceptable.

Conclusions reached by Product Safety Labs are:

Acute Oral Toxicity Study in Rats (MRID 45016901)

"An acute oral toxicity test was conducted with rats to determine the potential for Axenohl to produce toxicity from a single dose via the oral route. Based on the results of this study, the single dose acute oral LD50 of the test substance is greater than 5,000 mg/kg of bodyweight...All animals survived and appeared active and healthy throughout the study....There were no signs of gross toxicity, adverse pharmacologic effects or abnormal behavior. Gross necropsy findings at terminal sacrifice were unremarkable."

Acute Dermal Toxicity Study in Rats - Limit Test (MRID 45016902)

"An acute dermal toxicity test was conducted with rats to determine the potential for Axenohl to produce toxicity from a single topical application. Based on the results of this study, the single dose acute dermal LD50 of the test substance is greater than 5,000 mg/kg of body weight. ...All animals survived, gained weight and appeared active and healthy. There were no signs of gross toxicity, adverse pharmacologic effects or abnormal behavior. Gross necropsy findings at terminal sacrifice were unremarkable."

Primary Eye Irritation Study in Rabbits (MRID 45016903)

"A primary eye irritation test was conducted with rabbits to determine the potential for Axenohl to produce irritation from a single instillation via the ocular route. Based on the results of the study, the test substance is classified as mildly irritating to the eye....No corneal opacity or iritis was observed during the study...The overall incidence and severity of irritation decreased with time. All animals were free from ocular irritation within 72 hours."

Primary Skin Irritation Study in Rabbits (MRID 45016904)

"A primary skin irritation test was conducted with rabbits to determine the potential for Axenohl to produce irritation after a single topical application. Based on the results of this study, the test substance is classified as slightly irritating to the skin...Twenty-four hours after patch removal, well-defined erythema was observed at all three treated sites. Very slight edema was also evident the two rabbits. The overall incidence and severity of irritation decreased with time. All animals were free from irritation by Day 19 (study termination)...The Primary Dermal Irritation Index (PDII) calculated for this test substance was 1.7"

Dermal Sensitization Study in Guinea Pigs (Buehler Method) (MRID 45016905)

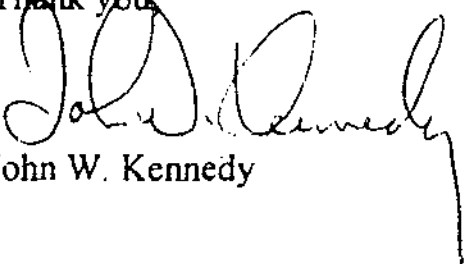
"A dermal sensitization test was conducted with guinea pigs to determine the potential for Axenohl to produce sensitization after repeated topical applications....Based on results of this study, the test substance is not considered to be a contact sensitizer. Historical data ...indicating a positive response to 0.04% DNCB in acetone validates the test system used in this study."

These studies may have been reviewed at this point.

Therefore, we request that the information include our comments and be reviewed by EPA's own in-house reviewers in the interest of saving time since the data is so clear that it passes the hard surface disinfectant criteria. I trust that this could be done with a minimum of time delay since this registration has been pending for over one year since it was initially submitted.

We appreciate very much your assistance in performing an expedited review and resolution for registration of Axen and Axenohl.

Thank you


John W. Kennedy



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 29 2000

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

ETI H₂O
Route 14, Box 1517
Lake City, FL 32054

Attention: John W. Kennedy, Agent

Subject: Axen
EPA File Symbol Number 72977-E
Your Application Dated June 16th, 2000

Axenhol
EPA File Symbol Number 72977-R
Your Application Dated June 16th, 2000

A review of your application packages has determined that additional information will be required in order for us to continue processing these applications.

PRODUCT CHEMISTRY/CSF FOR AXEN, EPA FILE SYMBOL 72977-E

1. The revised Confidential Statement of Formula dated June 23rd, 2000, is incomplete for the following reasons.
 - A. The amount of silver given in item 13a of the CSF is not consistent with the percentage of the silver shown in item 13b. This inconsistency must be resolved.
 - B. Item 17 of the CSF was not completed as required.
 - C. The nominal concentration of 0.0010% for silver given in item 13b of the CSF does not agree with the label declaration of 0.0012%.
 - D. Citric acid at a 4.8% level in the formulation cannot be justified as merely a stabilizing agent, for 12 ppm of silver ion. At this concentration, citric acid has well established antibacterial properties, and as such must be identified and declared as an active ingredient. (If this is not the case, please support your position by justification)

- E. It is suggested that the Axen basic CSF be written to show both the starting materials which include Axenhol and the final composition of Axen, on dilution of Axenhol with [REDACTED] and citric acid.
 - F. A complete chemical composition of the component [REDACTED] must be submitted for our review. The composition would include chemical names, CAS Reg. Nos. and percentages of each component.
 - G. Submit a corrected CSF and in column 13b enter the percentages by weight for each component.
- 2. The 830 Test Guideline Series covering test protocols for color, pH, Physical state and density of Axen were acceptable.
 - 3. The Accelerated Storage and Stability Study covering this product was also acceptable.

PRODUCT CHEMISTRY/CSF FOR AXENHOL, EPA FILE SYMBOL 72977-R

- 1. The revised Confidential Statement of Formula dated June 23rd, 2000, is incomplete for the following reasons.
 - A. The lower control limit for [REDACTED] given in item 14b cannot be higher than the nominal concentration for [REDACTED] as given in 13b.
 - B. The use of citric acid at concentration of 17.05% as a "stabilizer" for 0.240% of silver citrate. The high use levels of citric acid in both the Axenhol and Axen must also provide antimicrobial activity. Citric acid, therefore, should be treated as an active ingredient in the formulation and on the product labeling.
 - C. Submit a revised CSF and product labeling with the above corrections for our review for Axenhol.
- 2. The product chemistry and accelerated storage and stability data were completed and acceptable.

ALL INFORMATION CONTAINED HEREIN IS UNCLASSIFIED

129



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

| | | | |
|---|--|--|--|
| 1. Company/Product Number
EPA File Symbol 72977-E | | 2. EPA Product Manager
Marshall Swindell | 3. Proposed Classification
<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name)
AXEN | | PM#
33 | |
| 5. Name and Address of Applicant (Include ZIP Code)
ETI H2O
Rt. 14, Box 1517
Lake City, FL 32054
<input type="checkbox"/> Check if this is a new address | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____ | |

Section - II

| | |
|---|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input checked="" type="checkbox"/> Resubmission in response to Agency letter dated 11/29/00 | <input type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Corrections on CSF. Accounting for silver and explanation of anhydrous citric acid as a stabilizer explained. Starting materials to form Axen explained using Axenhol as a starting (technical) product.

Section - III

| | | | | | |
|---|---|--|---|--|----------------------------------|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging
<input type="checkbox"/> Yes
<input type="checkbox"/> No | Unit Packaging
<input type="checkbox"/> Yes
<input type="checkbox"/> No | Water Soluble Packaging
<input type="checkbox"/> Yes
<input type="checkbox"/> No | | <input type="checkbox"/> Metal | <input type="checkbox"/> Plastic |
| | | | | <input type="checkbox"/> Glass | <input type="checkbox"/> Paper |
| * Certification must be submitted | If "Yes" Unit Packaging wgt. No. per container | If "Yes" Package wgt. No. per container | | <input type="checkbox"/> Other (Specify) _____ | |
| 3. Location of Net Contents Information
<input type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container | 5. Location of Label Directions
<input type="checkbox"/> On Label
<input type="checkbox"/> On Labeling accompanying product | | |
| 6. Manner in Which Label is Affixed to Product
<input type="checkbox"/> Lithograph
<input type="checkbox"/> Paper glued
<input type="checkbox"/> Stenciled | | <input type="checkbox"/> Other _____ | | | |

Section - IV

| | | | |
|---|--|--|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | |
| Name
John W. Kennedy | | Title
Consultant to ETI H2O | |
| | | Telephone No. (Include Area Code)
John W. Kennedy Consultants 301-490-1600 | |
| Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | 8. Date Application Received
(Stamped) |
| 9. Signature
<i>John W. Kennedy</i> | | 3. Title
John W. Kennedy | |
| 10. Typed Name
John W. Kennedy | | 5. Date
12/8/00 | |
| | | | |

John W. Kennedy Consultants

13 "C" Street Suite G

Laurel, MD 20707

Phone: (301) 490-1600

Fax: (301) 490-5793

E-MAIL: John.Kennedy@ConsultantsJWK.com

December 7, 2000

Marshall Swindell
Product Manager 33
Antimicrobial Biogram Division (H7505C)
U. S. Environmental Protection Agency
Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202
Attn: Martha Terry

Subject: **Your letter of 11/29/00**
 Axen
 EPA File symbol No. 72977-E
 Axenohl
 EPA File symbol No. 72977-R

Dear Mr. Swindell,

JWKC Represents ETI-H2O. Dr. Ed Woolson has been the primary contact with ETI-H2O and we are responding to the subject letter.

Enclosed is the revised CSF for both Axen and Axenohl. The revision has taken into account the comments submitted in the chemistry review. The main function in the formulation is to keep the silver in solution. We request that citric acid be maintained as a stabilizer. At this time, ETIH2O wishes to drop the efficacy study for Enterococcus faecium since it is not necessary for the hard surface disinfectant registration.

We have not received the review for the hard surface disinfectant study run by

MicroBio Test, Inc. (Sterling VA.). Efficacy studies were submitted in November 1999. We understood during the meeting with you and Dr. Shamin on May 11, 2000 that the efficacy and toxicity studies had been reviewed and found acceptable. Perhaps we were wrong in our understanding. The MicroBio Test AOAC Use Dilution study was submitted on 11/99 and is identified as MRID 45016906. The summary of the data from that study indicates that **"Axenohl passes the AOAC Use Dilution Test when *S. aureus*, ATCC 6538; *S. choleraesuis*, ATCC 10708 and *P. aeruginosa*, ATCC 15442 are exposed to the test material for 10 minutes at 20±1 C. All of the sterility and viability control cultures met the resistance required to meet the criteria for a valid test. These conclusions are based on the observed data."**

In addition to the lack of review for the hard surface disinfectant study, we have not received reviews on the acute studies either. The EPA may have already reviewed the submitted in November 1999 for the technical, the same time as the MicroBio Test study. They are the acute oral (MRID 45016901), acute dermal (MRID 45016902), eye irritation (MRID 45016903), skin irritation (MRID 45016904) and dermal sensitization (MRID 45016905). Axenohl is non-toxic and Product Safety Labs listed it as a category 4 compound with slight eye irritation. The eye irritation for Axen (MRID 45016907) has been reviewed and found acceptable.

Conclusions reached by Product Safety Labs are:

Acute Oral Toxicity Study in Rats (MRID 45016901)

"An acute oral toxicity test was conducted with rats to determine the potential for Axenohl to produce toxicity from a single dose via the oral route. Based on the results of this study, the single dose acute oral LD50 of the test substance is greater than 5,000 mg/kg of bodyweight...All animals survived and appeared active and healthy throughout the study....There were no signs of gross toxicity, adverse pharmacologic effects or abnormal behavior. Gross necropsy findings at terminal sacrifice were unremarkable."

Acute Dermal Toxicity Study in Rats - Limit Test (MRID 45016902)

"An acute dermal toxicity test was conducted with rats to determine the potential for Axenohl to produce toxicity from a single topical application. Based on the results of this study, the single dose acute dermal LD50 of the test substance is greater than 5,000 mg/kg of body weight. ...All animals survived, gained weight and appeared active and healthy. There were no signs of gross toxicity, adverse pharmacologic effects or abnormal behavior. Gross necropsy findings at terminal sacrifice were unremarkable."

Primary Eye Irritation Study in Rabbits (MRID 45016903)

"A primary eye irritation test was conducted with rabbits to determine the potential for Axenohl to produce irritation from a single instillation via the ocular route. Based on the results of the study, the test substance is classified as mildly irritating to the eye....No corneal opacity or iritis was observed during the study...The overall incidence and severity of irritation decreased with time. All animals were free from ocular irritation within 72 hours."

Primary Skin Irritation Study in Rabbits (MRID 45016904)

"A primary skin irritation test was conducted with rabbits to determine the potential for Axenohl to produce irritation after a single topical application. Based on the results of this study, the test substance is classified as slightly irritating to the skin...Twenty-four hours after patch removal, well-defined erythema was observed at all three treated sites. Very slight edema was also evident the two rabbits. The overall incidence and severity of irritation decreased with time. All animals were free from irritation by Day 19 (study termination)...The Primary Dermal Irritation Index (PDII) calculated for this test substance was 1.7"

Dermal Sensitization Study in Guinea Pigs (Buehler Method) (MRID 45016905)

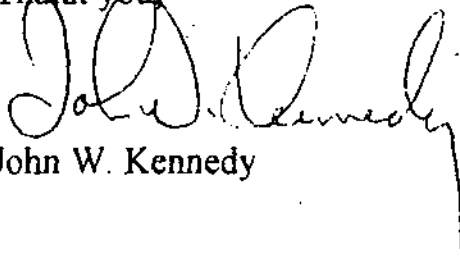
"A dermal sensitization test was conducted with guinea pigs to determine the potential for Axenohl to produce sensitization after repeated topical applications....Based on results of this study, the test substance is not considered to be a contact sensitizer. Historical data ...indicating a positive response to 0.04% DNCB in acetone validates the test system used in this study."

These studies may have been reviewed at this point.

Therefore, we request that the information include our comments and be reviewed by EPA's own in-house reviewers in the interest of saving time since the data is so clear that it passes the hard surface disinfectant criteria. I trust that this could be done with a minimum of time delay since this registration has been pending for over one year since it was initially submitted.

We appreciate very much your assistance in performing an expedited review and resolution for registration of Axen and Axenohl.

Thank you.

A handwritten signature in dark ink, appearing to read "John W. Kennedy", with a long, sweeping underline that extends to the right.

John W. Kennedy

Page ____ is not included in this copy.

Pages 145 through 146 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☒ The document is a duplicate of page(s) 138-139
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|---|--|--|
| 1. Company/Product Number
EPA File Symbol 72977-E | 2. EPA Product Manager
Marshall Swindell | 3. Proposed Classification
<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| Company/Product (Name)
AXEN | PM#
33 | |
| Name and Address of Applicant (Include ZIP Code)
ETI H2O
Rt. 14, Box 1517
Lake City, FL 32054 | | 5. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. _____

Product Name _____ |
| <input type="checkbox"/> Check if this is a new address | | |

Section - II

| | |
|---|---|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated: _____ |
| <input checked="" type="checkbox"/> Resubmission in response to Agency letter dated 11/29/00 | <input type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Corrections on CSF. Accounting for silver and explanation of anhydrous citric acid as a stabilizer explained. Starting materials to form Axen explained using Axenhol as a starting (Technical) product.

Section - III

| | | | | | |
|---|---|--|--------------------------------------|---|----------------------------------|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging
<input type="checkbox"/> Yes
<input type="checkbox"/> No | Unit Packaging
<input type="checkbox"/> Yes
<input type="checkbox"/> No | Water Soluble Packaging
<input type="checkbox"/> Yes
<input type="checkbox"/> No | | <input type="checkbox"/> Metal | <input type="checkbox"/> Plastic |
| | | | | <input type="checkbox"/> Glass | <input type="checkbox"/> Paper |
| * Certification must be submitted | If "Yes" Unit Packaging wgt. | No. per container | If "Yes" Package wgt | No. per container | Other (Specify) _____ |
| 3. Location of Net Contents Information
<input type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container | | 5. Location of Label Directions
<input type="checkbox"/> On Label
<input type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product
<input type="checkbox"/> Lithograph
<input type="checkbox"/> Paper glued
<input type="checkbox"/> Stenciled | | | <input type="checkbox"/> Other _____ | | |

Section - IV

| | | | |
|---|---------------------------------------|--|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | |
| Name
John W. Kennedy | Title
Consultant to ETI H2O | Telephone No. (Include Area Code)
John W. Kennedy Consultants 301-490-1600 | |
| Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | 6. Date Application Received
(Stamped) |
| 2. Signature
<i>John W. Kennedy</i> | 3. Title
John W. Kennedy | | |
| 4. Typed Name
John W. Kennedy | 5. Date
12/8/00 | | |



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|--|--|--|
| Company/Product Number
EPA File Symbol 72977-E | 2. EPA Product Manager
Marshall Swindell | 3. Proposed Classification
<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| Company/Product (Name)
AXEN | PM#
33 | |
| Name and Address of Applicant (Include ZIP Code)
ETIH20
Rt. 14, Box 1517
Lake City, FL 32054 | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____ |
| <input type="checkbox"/> Check if this is a new address | | |

Section - II

| | |
|---|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input checked="" type="checkbox"/> Resubmission in response to Agency letter dated 11/29/00 | <input type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Corrections on CSE. Accounting for silver and explanation of anhydrous citric acid as a stabilizer explained. Starting materials to form Axen explained using Axenhol as a starting (Technical) product.

Section - III

| | | | |
|--|---|--|--|
| Material This Product Will Be Packaged In: | | | |
| Child-Resistant Packaging
<input type="checkbox"/> Yes
<input type="checkbox"/> No | Unit Packaging
<input type="checkbox"/> Yes
<input type="checkbox"/> No | Water Soluble Packaging
<input type="checkbox"/> Yes
<input type="checkbox"/> No | 2. Type of Container
<input type="checkbox"/> Metal
<input type="checkbox"/> Plastic
<input type="checkbox"/> Glass
<input type="checkbox"/> Paper
<input type="checkbox"/> Other (Specify) _____ |
| Certification must be submitted
If "Yes" Unit Packaging wgt. No. per container | | If "Yes" Package wgt. No. per container | |
| Location of Net Contents Information
<input type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container | 5. Location of Label Directions
<input type="checkbox"/> On Label
<input type="checkbox"/> On Labeling accompanying product |
| Manner in Which Label is Affixed to Product
<input type="checkbox"/> Lithograph
<input type="checkbox"/> Paper glued
<input type="checkbox"/> Stenciled | | <input type="checkbox"/> Other _____ | |

Section - IV

| | | | |
|---|--|--|--|
| Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | |
| Name
John W. Kennedy | | Title
Consultant to ETIH20
John W. Kennedy Consultants | Telephone No. (Include Area Code)
301-490-1600 |
| Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | 6. Date Application Received
(Stamp) |
| Signature
<i>John W. Kennedy</i> | | 3. Title
John W. Kennedy | |
| Typed Name
John W. Kennedy | | 5. Date
12/8/00 | |



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☐ Other

DPP Identifier Number

Application for Pesticide - Section I

| | | |
|---|--|--|
| Company/Product Number
EPA File Symbol 72977-E | 2. EPA Product Manager
Marshall Swindell | 3. Proposed Classification
<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| Company/Product (Name)
AXEN | PM#
33 | |
| Name and Address of Applicant (Include ZIP Code)
ETI H2O
Rt. 14, Box 1517
Lake City, FL 32054 | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____ | |
| <input type="checkbox"/> Check if this is a new address | | |

Section - II

| | |
|---|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input checked="" type="checkbox"/> Resubmission in response to Agency letter dated 11/29/00 | <input type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

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Section - III

| | | | | | |
|---|---|--|--------------------------------------|---|----------------------------------|
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<input type="checkbox"/> Yes
<input type="checkbox"/> No | Unit Packaging
<input type="checkbox"/> Yes
<input type="checkbox"/> No | Water Soluble Packaging
<input type="checkbox"/> Yes
<input type="checkbox"/> No | | <input type="checkbox"/> Metal | <input type="checkbox"/> Plastic |
| | | | | <input type="checkbox"/> Glass | <input type="checkbox"/> Paper |
| * Certification must be submitted | If "Yes" Unit Packaging wgt. | No. per container | If "Yes" Package wgt. | No. per container | Other (Specify) _____ |
| 3. Location of Net Contents Information
<input type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container | | 5. Location of Label Directions
<input type="checkbox"/> On Label
<input type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product
<input type="checkbox"/> Lithograph
<input type="checkbox"/> Paper glued
<input type="checkbox"/> Stenciled | | | <input type="checkbox"/> Other _____ | | |

Section - IV

| | | | | | |
|---|--|---------------------------------------|--|--|--|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | | | | |
| Name
John W. Kennedy | | Title
Consultant to ETI H2O | | Telephone No. (Include Area Code)
John W. Kennedy Consultants 301-492-1600 | |
| Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | | | | 6. Data Application Received (Stamped) |
| Signature
John W. Kennedy | | 3. Title
John W. Kennedy | | | |
| Typed Name
John W. Kennedy | | 5. Date
12/8/00 | | | |

John W. Kennedy Consultants

13 "C" Street Suite G

Laurel, MD 20707

Phone: (301) 490-1600

Fax: (301) 490-5793

E-MAIL: John.Kennedy@consultants-jwk.com

December 7, 2000

Marshall Swindell
Product Manager 33
Antimicrobial Biogram Division (H7505C)
U. S. Environmental Protection Agency
Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA 22202
Attn: Martha Terry

Subject: **Your letter of 11/29/00**
 Axen
 EPA File symbol No. 72977-E
 Axenohl
 EPA File symbol No. 72977-R

Dear Mr. Swindell,

JWKC Represents ETI-H2O. Dr. Ed Woolson has been the primary contact with ETI-H2O and we are responding to the subject letter.

Enclosed is the revised CSF for both Axen and Axenohl. The revision has taken into account the comments submitted in the chemistry review. The main function in the formulation is to keep the silver in solution. We request that citric acid be maintained as a stabilizer. At this time, ETIH2O wishes to drop the efficacy study for Enterococcus faecium since it is not necessary for the hard surface disinfectant registration.

We have not received the review for the hard surface disinfectant study run by

MicroBio Test, Inc. (Sterling VA.). Efficacy studies were submitted in November 1999. We understood during the meeting with you and Dr. Shamin on May 11, 2000 that the efficacy and toxicity studies had been reviewed and found acceptable. Perhaps we were wrong in our understanding. The MicroBio Test AOAC Use Dilution study was submitted on 11/99 and is identified as MRID 45016906. The summary of the data from that study indicates that **"Axenohl passes the AOAC Use Dilution Test when *S. aureus*, ATCC 6538; *S. choleraesuis*, ATCC 10708 and *P. aeruginosa*, ATCC 15442 are exposed to the test material for 10 minutes at 20±1 C. All of the sterility and viability control cultures met the resistance required to meet the criteria for a valid test. These conclusions are based on the observed data."**

In addition to the lack of review for the hard surface disinfectant study, we have not received reviews on the acute studies either. The EPA may have already reviewed the submitted in November 1999 for the technical, the same time as the MicroBio Test study. They are the acute oral (MRID 45016901), acute dermal (MRID 45016902), eye irritation (MRID 45016903), skin irritation (MRID 45016904) and dermal sensitization (MRID 45016905). Axenohl is non-toxic and Product Safety Labs listed it as a category 4 compound with slight eye irritation. The eye irritation for Axen (MRID 45016907) has been reviewed and found acceptable.

Conclusions reached by Product Safety Labs are:

Acute Oral Toxicity Study in Rats (MRID 45016901)

"An acute oral toxicity test was conducted with rats to determine the potential for Axenohl to produce toxicity from a single dose via the oral route. Based on the results of this study, the single dose acute oral LD50 of the test substance is greater than 5,000 mg/kg of bodyweight...All animals survived and appeared active and healthy throughout the study....There were no signs of gross toxicity, adverse pharmacologic effects or abnormal behavior. Gross necropsy findings at terminal sacrifice were unremarkable."

Acute Dermal Toxicity Study in Rats - Limit Test (MRID 45016902)

"An acute dermal toxicity test was conducted with rats to determine the potential for Axenohl to produce toxicity from a single topical application. Based on the results of this study, the single dose acute dermal LD50 of the test substance is greater than 5,000 mg/kg of body weight. ...All animals survived, gained weight and appeared active and healthy. There were no signs of gross toxicity, adverse pharmacologic effects or abnormal behavior. Gross necropsy findings at terminal sacrifice were unremarkable."

Primary Eye Irritation Study in Rabbits (MRID 45016903)

"A primary eye irritation test was conducted with rabbits to determine the potential for Axenohl to produce irritation from a single instillation via the ocular route. Based on the results of the study, the test substance is classified as mildly irritating to the eye....No corneal opacity or iritis was observed during the study...The overall incidence and severity of irritation decreased with time. All animals were free from ocular irritation within 72 hours."

Primary Skin Irritation Study in Rabbits (MRID 45016904)

"A primary skin irritation test was conducted with rabbits to determine the potential for Axenohl to produce irritation after a single topical application. Based on the results of this study, the test substance is classified as slightly irritating to the skin...Twenty-four hours after patch removal, well-defined erythema was observed at all three treated sites. Very slight edema was also evident the two rabbits. The overall incidence and severity of irritation decreased with time. All animals were free from irritation by Day 19 (study termination)...The Primary Dermal Irritation Index (PDII) calculated for this test substance was 1.7"

Dermal Sensitization Study in Guinea Pigs (Buehler Method) (MRID 45016905)

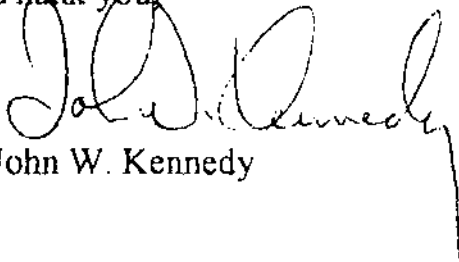
"A dermal sensitization test was conducted with guinea pigs to determine the potential for Axenohl to produce sensitization after repeated topical applications....Based on results of this study, the test substance is not considered to be a contact sensitizer. Historical data ...indicating a positive response to 0.04% DNCB in acetone validates the test system used in this study."

These studies may have been reviewed at this point.

Therefore, we request that the information include our comments and be reviewed by EPA's own in-house reviewers in the interest of saving time since the data is so clear that it passes the hard surface disinfectant criteria. I trust that this could be done with a minimum of time delay since this registration has been pending for over one year since it was initially submitted.

We appreciate very much your assistance in performing an expedited review and resolution for registration of Axen and Axenohl.

Thank you,

A handwritten signature in dark ink, appearing to read "John W. Kennedy", with a long, thin vertical line extending downwards from the end of the signature.

John W. Kennedy

Page ____ is not included in this copy.

Pages 154 through 155 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☒ The document is a duplicate of page(s) 138-139.
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

AXEN[®]

Stabilized Ionic Silver Hard Surface Disinfectant

AXEN[®] Disinfectant Pump Spray Kills Viruses and bacteria on environmental surfaces in your home and public places. It eliminates germs and odors on hard nonporous surfaces that you come in contact with everyday. Use AXEN[®] Disinfectant Spray:

In empty garbage cans

In diaper pails

In pet areas

In empty hampers

In sick rooms

On doorknobs

Under sinks

Around toilet areas

Fast/Easy/Effective: Use on finished surfaces in basements, closets, attics, laundry rooms, storage areas, vacation homes, boat interiors, shower stalls and recycling bins. Excellent for controlling mold and mildew on mattresses, pillows and shower curtains.

Bacteria and Fungi:

Staph and Strep

Salmonella

E. Coli

Campylobacter

Athlete's foot fungus

Viruses:

Rhinovirus (the leading cause of the common cold)

Rotavirus (the leading cause of infectious diarrhea in children)

Respiratory Syncytial Virus (the leading cause of lower respiratory infections in children)

Poliovirus Type 1 - Adenovirus type 2

Herpes simplex Virus types 1 & 2 - Hepatitis A

Ingredients

Active Ingredients:

* Silver 0.0012 %

Inert ingredients 99.9988 %

Total : 100.0000 %

* electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN
PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Avoid contact with eyes. Wash thoroughly with soap and water after handling. Avoid contamination of food and feed. Do not leave package where children and animals may gain access.

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES, flush with plenty of water. Get medical attention if irritation persists.

IF ON SKIN, wash with soap and water. Get medical attention if irritation persists.

SUBMISSION BAR CODE # 5585171REVIEWER M TerryCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 72977-E PM 33 ACTION CODE 189DESCRIPTOR Supporting Data

[] CHILD RESISTANT PACKAGING: [] CERTIFICATION
[] NON-RESIDENTIAL USE ONLY
[] NOT APPLICABLE

REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL

PROPOSED CLASSIFICATION: [] GENERAL [] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

| | | |
|----|----|----|
| 06 | 16 | 00 |
|----|----|----|

| | | |
|----|----|----|
| 08 | 23 | 00 |
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| | | |
|----|----|----|
| 08 | 05 | 00 |
|----|----|----|

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[] CITE-ALL
[] SELECTIVE
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

[] SUBMITTED
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

10

RESPONSE DATE

NOV 29 2000



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

NOV 29 2000

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

ETI H₂O
Route 14, Box 1517
Lake City, FL 32054

Attention: John W. Kennedy, Agent

Subject: Axen
EPA File Symbol Number 72977-E
Your Application Dated June 16th, 2000

Axenhol
EPA File Symbol Number 72977-R
Your Application Dated June 16th, 2000

A review of your application packages has determined that additional information will be required in order for us to continue processing these applications.

PRODUCT CHEMISTRY/CSF FOR AXEN, EPA FILE SYMBOL 72977-E

1. The revised Confidential Statement of Formula dated June 23rd, 2000, is incomplete for the following reasons.
 - A. The amount of silver given in item 13a of the CSF is not consistent with the percentage of the silver shown in item 13b. This inconsistency must be resolved.
 - B. Item 17 of the CSF was not completed as required.
 - C. The nominal concentration of 0.0010% for silver given in item 13b of the CSF does agree with the label declaration of 0.0012%.
 - D. Citric acid at a 4.8% level in the formulation cannot be justified as merely a stabilizing agent, for 12 ppm of silver ion. At this concentration, citric acid has well established antibacterial properties, and as such must be identified and declared as an active ingredient. (If this is not the case, please support your position by justification).

- E. It is suggested that the Axen basic CSF be written to show both the starting materials which include Axenhol and the final composition of Axen, on dilution of Axenhol with [REDACTED] and citric acid.
 - F. A complete chemical composition of the component [REDACTED] must be submitted for our review. The composition would include chemical names, CAS Reg. Nos. and percentages of each component.
 - G. Submit a corrected CSF and in column 13b enter the percentages by weight for each component.
- 2. The 830 Test Guideline Series covering test protocols for color, pH, Physical state, and density of Axen were acceptable.
 - 3. The Accelerated Storage and Stability Study covering this product was also acceptable.

PRODUCT CHEMISTRY/CSF FOR AXENHOL, EPA FILE SYMBOL 72977-R

- 1. The revised Confidential Statement of Formula dated June 23rd, 2000, is incomplete for the following reasons.
 - A. The lower control limit for [REDACTED] given in item 14b cannot be higher than the nominal concentration for [REDACTED] as given in 13b.
 - B. The use of citric acid at concentration of 17.05% as a "stabilizer" for 0.24 % of silver citrate. The high use levels of citric acid in both the Axenhol and Axen must also provide antimicrobial activity. Citric acid, therefore, should be treated as an active ingredient in the formulation and on the product labeling.
 - C. Submit a revised CSF and product labeling with the above corrections for our review for Axenhol.
- 2. The product chemistry and accelerated storage and stability data were completed and acceptable.

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EFFICACY:

The submitted efficacy data were found to be deficient and unacceptable. Please refer to the enclosed copy of the efficacy review under "SUMMARY OF INFORMATION REVIEWED AND FINDINGS/CONCLUSIONS" for your corrections and guidance.

LABELING:

The Agency reserves a full label review at this time until the above deficiencies have been resolved. Just a reminder that additional information/data may be required to support your application after the corrected efficacy data have been submitted and reviewed.

ADMINISTRATIVE (for both products):

Submit a data matrix for the Technical Grade Silver Active Ingredient. Refer the Agency's Silver RED document. You must also submit appropriate data compensation paperwork for the Citric Acid active ingredient. If you were using an unregistered source of citric acid and the Selective MOS, you must submit a data matrix for the TGAI Citric Acid.

If you have any questions concerning this letter, please contact Karen M. Leavy-Munk at (703)-308-6237.

Sincerely,



Marshall Swindell
Product Manager 33
Regulatory Management Branch I
Antimicrobial Division(7505C)

AUG 7 2000

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

ETI H20
RT. 14, BOX 1517
LAKE CITY, FL 32054

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 08/03/00. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

John W. Kennedy Consultants

13 "C" Street Suite G

Laurel, MD 20707

Phone: (301) 490-1600

Fax: (301) 490-5793

E-MAIL: JohnKennedyConsultants@hotmail.com

June 16, 2000

To: Marshall Swindell

Product Manager 33

Antimicrobial Division (H7505C)

Office of Pesticide Programs

Environmental Protection Agency

Crystal Mall No. 2

1921 Jefferson Davis Highway

Arlington, VA 22202

Subject: AXEN - EPA File Symbol 72977-E ✓

AXENOHL - EPA File Symbol 72977-R

Our Meetings of 6/15/00, Your Letter of 5/10/00 With

Reviews of 3/31/00 and 5/8/00 and Telephone Note of 4/19/00.

Dear Mr. Swindell

John W. Kennedy Consultants (JWKC) represents ETI H2O Inc. in all matters dealing with pesticide clearances.

AXEN is an end-use product formulated by the dilution of AXENOHL. The chemistry of AXEN passed the front end screen, then was reviewed by the EPA and found acceptable (your letter of May 10, 2000) except for minor deficiencies, which we have corrected. The product chemistry of AXENOHL did not make it through the front end screen because of minor discrepancies which we have corrected (see resubmission transmittal document). The data review of the chemistry for AXENOHL should not be necessary since the AXENOHL submission is almost exactly the same as the AXEN chemistry.

We have also included an Accelerated Storage Stability Study of AXENOHL and AXEN along with the chemical properties of AXENOHL. The same Transmittal Document has an efficacy study for AXENOHL.

The question of whether the active is a new chemical was addressed using the chemistry conducted by Bio-Analytical Services, Inc. under the direction of Dr. Ed Woolson.

AXENOHL and AXEN are a combination of electrolytically generated silver ions and stabilizers. The attached data demonstrated that the active is ionic silver (attachment #1)

We then discussed the claim that the formulation is a "stabilized ionic silver". There was agreement and the revised labels reflect the discussion (Attachment # 2)

Changes have been made to the Confidential Statement of the Formula (CSF) for AXEN as requested in your May 10, 2000 memo and EPA reviews of 5/08/00. We have also attached a new CSF for AXENOH (Attachment # 3).

The efficacy studies was rejected [07] because of minor deficiencies which have been corrected (see Resubmission Transmittal Document)

The toxicology review for AXEN included only the eye irritation study, which was found acceptable to the EPA in a memo dated 5/08/00: Subject D263138. As noted, the AXEN is the diluted form of AXENOH and the full compliment of toxicology studies were conducted on the "technical" (AXENOH). From our review of the studies, the AXENOH should be category IV and therefore AXEN would also be category IV. The toxicology studies for AXENOH can therefore satisfy the data requirements for AXEN.

The studies listed below are for AXENOH, the technical concentrate (ca. 2,400 ppm Ag⁺):

| <u>Study</u> | <u>Our Conclusions</u> | <u>MRID Numbers</u> |
|--------------------------|--|---------------------|
| 1. Acute oral Toxicity | LD50 >5,000 mg/Kg | 45016901 |
| 2. Acute Dermal Toxicity | LD50 >5,000 mg/Kg | 45016902 |
| 3. Dermal Sensitization | Not a contact sensitizer | 45016905 |
| 4. Ocular Irritation | Mildly irritation. Irritation cleared by 72 hours. Category 3. | 45016903 |
| 5. Dermal Irritation | Slight irritation at 72 hours which cleared. | 45016904 |

For the diluted product, AXEN, at proposed use level concentrations (ca. 12 ppm Ag⁺) the ocular irritation study indicated the product to be practically non-irritating with the irritation cleared by 24 hours. (MRID 450165-01)

SUMMARY

The conclusion of the discussion was that the active is ionic silver and not a new chemical as an "old" chemical, the following should be exempt from the following battery of studies rerequested in your previous letter:

1. Subchronic Tox.
2. Chronic Tox (teratology)
3. Mutagenicity
4. Bird LD 50
5. Fish LC 50
6. Invertebrate LC50

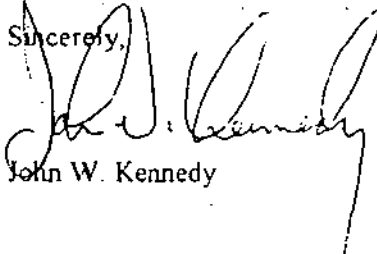
A new philosophy is being discussed at the EPA and is leaning toward requiring a risk assessment for any new uses of a chemical. Mr. Swindell indicated that it may be necessary to conduct a risk assessment using additional toxicology studies. We do not believe this is necessary for the product with such low toxicity, especially since the use pattern is only as a hard surface disinfectant.

Another important factor to be considered in the use of a product containing a silver ion is that this unique disinfectant can be rotated with other classes of disinfectants to control resistant organisms (bacteria, fungus, virus) in an integrated approach. Any risk assessment should take into account pesticides that can be used in rotation to prevent resistance from occurring.

We suggest that the EPA review both the AXEN and AXENOHLL applications all at once since the "formulated" AXEN is only a dilution of the AXENOHLL. In certain formulations, the addition of a low toxicity surfactant such as [REDACTED] which is cleared by the EPA, may be added in small amounts and such a minor addition should not change the tox category for the product.

It should be pointed out that ionic silver is generated in swimming pool cleaning systems without any regulation. The proposed use of the subject products will be as a hard surface disinfectant at extremely low rates (12 ppm). The benefit involved using a metal ion at such low rates would far exceed any risks for such a use and any risk assessment should take that fact into consideration.

Sincerely,


John W. Kennedy

AXEN OHLL SURFACTANT APPLICATION IS NOT INCLUDED

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TRANSMITTAL DOCUMENT
OF STUDY RESULTS

NAME AND ADDRESS OF SUBMITTER:

ETI H2O

Route, Box 315

Lake City, IL 32054

REGULATORY ACTION:

EPA File Symbol 72977-E (AXEN)

TRANSMITTAL DATE:

(See File Symbol 72977-R for Storage Stability)

LIST OF SUBMITTED STUDIES:

45182001

Study No.

VOLUME 1 - Determination of Color, pH, Physical State
Odor and Density of AXEN

45182002

Study No.

VOLUME 2 - Accelerated Storage Stability of
AXENOHI and AXEN

COMPANY OFFICIAL:

John W. Kennedy

TYPED NAME

SIGNATURE

COMPANY NAME:

John W. Kennedy Consultants

COMPANY CONTACT:

John W. Kennedy

TYPED NAME

(301) 490-1600

TELEPHONE

AXEN®

Stabilized Ionic Silver Hard Surface Disinfectant

AXEN® Disinfectant Pump Spray Kills Viruses and bacteria on environmental surfaces in your home and public places. It eliminates germs and odors on hard nonporous surfaces that you come in contact with everyday. Use AXEN® Disinfectant Spray:

In empty garbage cans

In pet areas

In sick rooms

Under sinks

In diaper pails

In empty hampers

On doorknobs

Around toilet areas

Fast/Easy/Effective: Use on finished surfaces in basements, closets, attics, laundry rooms, storage areas, vacation homes, boat interiors, shower stalls and recycling bins. Excellent for controlling mold and mildew on mattresses, pillows and shower curtains.

Bacteria and Fungi:

Staph and Strep

Salmonella

E. Coli

Campylobacter

Athlete's foot fungus

Viruses:

Rhinovirus (the leading cause of the common cold)

Rotavirus (the leading cause of infectious diarrhea in children)

Respiratory Syncytial Virus (the leading cause of lower respiratory infections in children)

Poliovirus Type 1 - Adenovirus type 2

Herpes simplex Virus types 1 & 2 - Hepatitis A

Ingredients

Active Ingredients:

* Silver 0.0012 %

Inert ingredients 99.9988 %

Total : 100.0000 %

* electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN
PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Harmful if swallowed. Avoid contact with eyes. Wash thoroughly with soap and water after handling. Avoid contamination of food and feed. Do not leave package where children and animals may gain access.

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES, flush with plenty of water. Get medical attention if irritation persists.

IF ON SKIN, wash with soap and water. Get medical attention if irritation persists.

10/10/00 A.T.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of Axen

DP Barcode: D268937

Reg. No. or File Symbol: 72977-E

Manufacturing-use []

End-use Product [X]

Active Ingredient Composition:

*Silver.....0.0012%

*electrolytically generated silver ions

TO: Marshall Swindell PM 33

FROM: Alex Traska, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510C)

ET 10/10/00

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

Karen P. Hicks
10/31/00

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510 C)

BACKGROUND:

This re-submission in support of the new product registration, for the subject hard surface disinfectant spray, was submitted by John W. Kennedy

Consultants, Inc. on behalf of the registrant, ETI H2O, Inc.

The registrant, in this re-submission, is responding to the May 10, 2000 Agency letter in which specific revisions and corrections were requested to the CSF and label.

The following documents were submitted and examined in the chemistry review of this submission: agent's cover letter dated June 16, 2000, revised Basic Formulation CSF dated 6/23/00, product label dated 10/10/00 by the reviewer, Product Chemistry Data Series 830 covering determinations of color, pH, physical state, odor, density and accelerated stability studies.

FINDINGS:

1. The 830 Test Guideline Series covering test protocols for color, pH, physical state and density of **Axen** were acceptable.
2. The Accelerated Storage Stability Study covering this product was also complete and acceptable.
3. The amount of silver given in item 13 a of the CSF is not consistent with the percentage of the silver shown in item 13b. This inconsistency must be resolved.
4. Item 17 of the CSF was not completed as required.
5. The nominal concentration of 0.0010% for silver given in item 13b of the CSF does not agree with the label declaration of 0.0012%.
6. Citric acid at a 4.8% level in the formulation cannot be justified as merely a stabilizing agent, for 12 ppm of silver ion. At this concentration, citric acid has well established antibacterial properties, and as such must be identified and declared as an active ingredient. *(If this is not the case, please support your position by justification).*
7. It is suggested that the **Axen** Basic CSF be written to show both the starting materials which include **Axenohl** and the final composition of **Axen**, on dilution of **Axenohl** with [REDACTED] and citric acid.

RECOMMENDATIONS:

This re-submission, in support of the new product registration of **Axen** , is not accepted.

Deficiencies noted under Findings must be addressed by the registrant.

10/10/00 AT

167

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

JUL 12 2000

ETI H20
RT. 14, BOX 1517
LAKE CITY, FL 32054

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 07/07/00. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected study [01] :

A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

Rejected study [02] :

A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific

guidance.

171

171

John W. Kennedy Consultants

13 "C" Street Suite G

Laurel, MD 20707

Phone: (301) 490-1600

Fax: (301) 490-5793

E-MAIL: JohnKennedyConsultants@hotmail.com

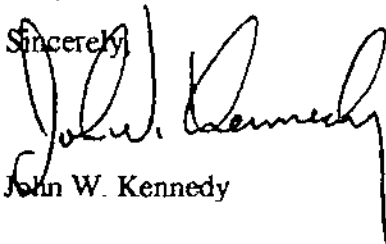
August 2, 2000

Front End Screen (PR 86-5)
Antimicrobial Division (7505C)
Office of Pesticide Programs
Environmental Protection Agency
Crystall Mall No. 2
1921 Jefferson Davis Highway
Arlington, VA 22202

Subject: AXEN - EPA File Symbol 72977-E

This is a resubmission based on your letter of July 12, 2000.

Sincerely,



John W. Kennedy



JOHN W. KENNEDY CONSULTANTS, INC.

13101 Street, Suite G, Luthi, MD 20707
Telephone: (301) 480-1800, FAX: (301) 480-8793

Dec. 9, 1999

450169-00

Marshall Swindell
Product Manager 33
Antimicrobial Biogram Division (H7505C)
U.S. Environmental Protection Agency
Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA. 22202

Subject: New Registration For AXENOHL
Technical Product For Formulation of AXEN
Company Number 72977 - R

Dear Marshall,

John W. Kennedy Consultants represents ETI H2O in all matters dealing with pesticide and Food and Drug clearances.

Attached are the following data to support both the technical (AXENOHL) and the formulated product (AXEN):

- (1) Application for Pesticide
- (2) Certification with Respect to Citation of Data
- (3) Proposed Label
- (4) Data Matrix
- (5) Data Submissions
- (6) Confidential Statement of Formula

Please note that ETI H2O is going the Selective Method. The Data Matrix for the two products and one toxicology study is all that separate the two submissions except for Chemistry.

We believe that these two submissions qualify for "FAST TRACK".

Best regards,

John W. Kennedy
John W. Kennedy

- | | |
|-----------------------------------|-------------|
| 1. Acute Oral Toxicity | 45016901 |
| 2. Acute Dermal Toxicity | 45016902 |
| 3. Primary Eye Irritation | 45016903 |
| 4. Primary Skin Irritation | 45016904 |
| 5. Dermal Sensitization | 45016905 |
| 6. Product Identity & Composition | Reject (06) |
| 7. Disinfection Efficacy | Reject (07) |
| 8. AOAC Use Dilution | 45016906 |

AXEN - E

Primary Eye Irritation Study in Rabbits
Product Identity and Composition

45016501
45016502

SUBMISSION BAR CODE # 5582714REVIEWER K. Leary-MunkCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 72977-E PM 33 ACTION CODE 189DESCRIPTOR Studies

[] CHILD RESISTANT PACKAGING: [] CERTIFICATION
[] NON-RESIDENTIAL USE ONLY
[] NOT APPLICABLE

REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL

PROPOSED CLASSIFICATION: [] GENERAL [] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

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| 06 | 16 | 00 |
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| 07 | 10 | 00 |
|----|----|----|

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[] CITE-ALL
[] SELECTIVE
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

[] SUBMITTED
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATUS

RESPONSE CODE

18

RESPONSE DATE

JUL 20 2000 ✓

33

This is an ACCEPTED submission.

One copy of the PPC diagnosis and one copy of the annotated bibliography are provided for your files. The PPC has already mailed out the submitter's copy of the two documents.

4.11

This is a PARTIALLY ACCEPTED/~~COMPLETELY REJECTED~~ submission.

A copy of the PPC diagnosis and the annotated bibliography are provided for your files. A second copy is provided for your use in corresponding with the data submitter.

[18/9-KL]

At return this package to
the consultant

✓

Page ___ is not included in this copy.

Pages 176 through 178 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☒ The document is a duplicate of page(s) 162-164.
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.



JOHN W. KENNEDY CONSULTANTS, INC.

13 "C" STREET, SUITE G, LAUREL, MD 20707
TELEPHONE: (301) 450-1600, FAX: (301) 450-5793

Dec. 9, 1999

450165-00

Marshall Swindell
Product Manager 33
Antimicrobial Biogram Division (H7505C)
U.S. Environmental Protection Agency
Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA. 22202

Subject: New Registration For AXENOHL
Technical Product For Formulation of AXEN
Company Number 72977 - R

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- (3) Proposed Label
- (4) Data Matrix
- (5) Data Submissions
- (6) Confidential Statement of Formula

Please note that ETI H2O is going the Selective Method. The Data Matrix for the two products and one toxicology study is all that separate the two submissions except for Chemistry.

We believe that these two submissions qualify for "FAST TRACK".

Best regards,

John W. Kennedy

- | | | |
|-----------------------------------|----------|-------------|
| 1. Acute Oral Toxicity | 45016901 | |
| 2. Acute Dermal Toxicity | 45016902 | |
| 3. Primary Eye Irritation | 45016903 | |
| 4. Primary Skin Irritation | 45016904 | |
| 5. Dermal Sensitization | 45016905 | |
| 6. Product Identity & Composition | | Reject (06) |
| 7. Disinfection Efficacy | | Reject (07) |
| 8. AOAC Use Dilution | 45016906 | |

AXEN - E

Primary Eye Irritation Study in Rabbits
Product identity and Composition

46016501
46016502

TRANSFERRAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

ETI H2O
Rt. 14, Box 1517
Lake City, FL 32054

REGULATORY ACTION:

EPA File Symbol 72977-E (AXEN)

TRANSMITTAL DATE:

(See File Symbol 72977-B for Storage Stability)

LIST OF SUBMITTED STUDIES:

REJECT (01)

STUDY NO.

VOLUME 1 - Determination of Color, pH, Physical State
Odor and Density of AXEN.

REJECT (02)

STUDY NO.

VOLUME 2 - Accelerated Storage Stability of
AXENOHL and AXEN.

COMPANY OFFICIAL:

John W. Kennedy

TYPED NAME

John W. Kennedy

SIGNATURE

COMPANY NAME:

John W. Kennedy Consultants

COMPANY CONTACT:

John W. Kennedy

TYPED NAME

(301) 490-1600

TELEPHONE

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

JUL 12 2000

ETI H20
RT. 14, BOX 1517
LAKE CITY, FL 32054

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 07/07/00. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

We are unable to accept your data submittal for further processing and review, because of the significant deficiencies noted below. It is being returned to you for correction. If deficiencies were found which apply to your overall submission, they are described immediately following this paragraph. If problems are found with individual studies, they are described below linked to the study identifier found on the enclosed copy of your bibliography.

Rejected study [01] :

A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific guidance.

Rejected study [02] :

A statement of compliance or non-compliance with the Good Laboratory Practices Standards contained in 40 CFR160 is required for all studies (except range finding studies and supplements to previously submitted studies) submitted to EPA. This statement must appear as page 3 of all studies, and must be signed and dated by the study sponsor, the study submitter, and the study director. Please see 40 CFR 160.12 for specific

guidance.

180

180

Page ____ is not included in this copy.

Pages 183 through 185 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☒ The document is a duplicate of page(s) 162-164.
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.



JOHN W. KENNEDY CONSULTANTS, INC.

15 "C" STREET, SUITE G, LARGO, MD 20777
TELEPHONE: (301) 450-1600, FAX: (301) 450-5795

Dec. 9, 1999

450169-00

Marshall Swindell
Product Manager 33
Antimicrobial Biogram Division (H7505C)
U.S. Environmental Protection Agency
Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA. 22202

Subject: New Registration For AXENOHL
Technical Product For Formulation of AXEN
Company Number 72977 - R

Dear Marshall,

John W. Kennedy Consultants represents ETI H2O in all matters dealing with pesticide and Food and Drug clearances.

Attached are the following data to support both the technical (AXENOHL) and the formulated product (AXEN):

- (1) Application for Pesticide
- (2) Certification with Respect to Citation of Data
- (3) Proposed Label
- (4) Data Matrix
- (5) Data Submissions
- (6) Confidential Statement of Formula

Please note that ETI H2O is going the Selective Method. The Data Matrix for the two products and one toxicology study is all that separate the two submissions except for Chemistry.

We believe that these two submissions qualify for "FAST TRACK".

Best regards,

John W. Kennedy
John W. Kennedy

1. Acute Oral Toxicity 45016901
2. Acute Dermal Toxicity 45016902
3. Primary Eye Irritation 45016903
4. Primary Skin Irritation 45016904
5. Dermal Sensitization 45016905
6. Product Identity & Composition Reject (06)
7. Disinfection Efficacy Reject (07)
8. AOAC Use Dilution 45016906

AXEN - E

Primary Eye Irritation Study in Rabbits 46016501
Product Identity and Composition 46016502

RECEIVED

NAME AND ADDRESS OF THE OWNER:

ETI H2O

P.O. Box 1517

Lake City, FL 32054

REGULATORY ACTION:

EPA File Symbol 72977-E (AXEN)

TRANSMITTAL DATE:

(See File Symbol 72977-R for Storage Stability)

LIST OF SUBMITTED STUDIES:

JECT (01)

STUDY NO.

VOLUME 1 - Determination of Color, pH, Physical State
Odor and Density of AXEN.

JECT (02)

STUDY NO.

VOLUME 2 - Accelerated Storage Stability of
AXENOHI and AXEN.

COMPANY OFFICIAL:

John W. Kennedy

TYPED NAME



SIGNATURE

COMPANY NAME:

John W. Kennedy Consultants

COMPANY CONTACT:

John W. Kennedy

TYPED NAME

(301) 490-1600

TELEPHONE

Administrative

Materials

ATTACHMENT #1 # 2

THIS IS NOT A DATA SUBMISSION,
ONLY CLARIFICATION OF
PREVIOUSLY SUBMITTED DATA
REQUESTED BY THE EPA

SEE ATTACHED LETTER (Dated 5/26/00)
TO MARSHALL SWINDEL
FROM DR. ED WILLSON.

Page ____ is not included in this copy.

Pages 190 through 214 are not included in this copy.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

☒ FIFRA registration data.

____ The document is a duplicate of page(s) ____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

ATTACHMENT #3

LABELS FOR

AXEN

AND

AXENOHIL

AXEN[®]

Stabilized Ionic Silver Hard Surface Disinfectant

AXEN[®] Disinfectant Pump Spray Kills Viruses and bacteria on environmental surfaces in your home and public places. It eliminates germs and odors on hard nonporous surfaces that you come in contact with everyday. Use AXEN[®] Disinfectant Spray:

In empty garbage cans

In diaper pails

In pet areas

In empty hampers

In sick rooms

On doorknobs

Under sinks

Around toilet areas

Fast/Easy/Effective: Use on finished surfaces in basements, closets, attics, laundry rooms, storage areas, vacation homes, boat interiors, shower stalls and recycling bins. Excellent for controlling mold and mildew on mattresses, pillows and shower curtains.

Bacteria and Fungi:

Staph and Strep

Salmonella

E. Coli

Campylobacter

Athlete's foot fungus

Viruses:

Rhinovirus (the leading cause of the common cold)

Rotavirus (the leading cause of infectious diarrhea in children)

Respiratory Syncytial Virus (the leading cause of lower respiratory infections in children)

Poliovirus Type 1 - Adenovirus type 2

Herpes simplex Virus types 1 & 2 - Hepatitis A

Ingredients

Active Ingredients:

* Silver 0.0012 %

Inert ingredients 99.9988 %

Total : 100.0000 %

* electrolytically generated Silver ions

**KEEP OUT OF REACH OF CHILDREN
PRECAUTIONARY STATEMENTS:
HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

CAUTION

Harmful if swallowed. Avoid contact with eyes. Wash thoroughly with soap and water after handling. Avoid contamination of food and feed. Do not leave package where children and animals may gain access.

STATEMENT OF PRACTICAL TREATMENT

IF IN EYES, flush with plenty of water. Get medical attention if irritation persists.

IF ON SKIN, wash with soap and water. Get medical attention if irritation persists.

AXEN[®]

Stabilized Ionic Silver Hard Surface Disinfectant

AXEN[®] Disinfectant Pump Spray Kills Viruses and bacteria on environmental surfaces in your home and public places. It eliminates germs and odors on hard nonporous surfaces that you come in contact with everyday. Use AXEN[®] Disinfectant Spray:

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Herpes simplex Virus types 1 & 2 - Hepatitis A

Ingredients

Active Ingredients:

| | |
|-------------------|-----------|
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| Inert ingredients | 99.9988 % |

Total : 100.0000 %

* electrolytically generated Silver ions

KEEP OUT OF REACH OF CHILDREN
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Harmful if swallowed. Avoid contact with eyes. Wash thoroughly with soap and water after handling. Avoid contamination of food and feed. Do not leave package where children and animals may gain access.

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IF IN EYES, flush with plenty of water. Get medical attention if irritation persists.

IF ON SKIN, wash with soap and water. Get medical attention if irritation persists.

ATTACHMENT #4

CONFIDENTIAL
STATEMENTS OF
FORMULA FOR

AXEN ✓

AND

AXENOHL

FOIPA

SUBMISSION BAR CODE # 5574918REVIEWER P HastyCODING FORM FOR APPLICATIONS FOR REGISTRATION/AMENDMENTSFILE SYMBOL/REG NO. 72977-E PM 33 ACTION CODE 188DESCRIPTOR New Application

[] CHILD RESISTANT PACKAGING: [] CERTIFICATION
[] NON-RESIDENTIAL USE ONLY
[] NOT APPLICABLE

REGISTRATION TYPE: [] CONDITIONAL [] UNCONDITIONAL

PROPOSED CLASSIFICATION: [] GENERAL [] RESTRICTED USE

DATE ON APPLICATION

EPA RECEIVE DATE

PM RECEIVE DATE

| | | |
|----|----|----|
| 11 | 28 | 99 |
|----|----|----|

| | | |
|----|----|----|
| 01 | 11 | 00 |
|----|----|----|

| | | |
|----|----|----|
| 01 | 27 | 00 |
|----|----|----|

METHOD OF SUPPORT

FORMULATORS EXEMPTION

[] CITE-ALL
[] SELECTIVE
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

[] -SUBMITTED
[] NOT SUBMITTED
[] NOT APPLICABLE
[] INCORRECT/RESUB

REVIEW(S) REQUESTED

DATA
PACK #DATE
SENTDUE
DATEDATE
RETURNED

CHEMISTRY

EFFICACY

TOXICOLOGY

HED TOX.

ENVIRON. FATE

FISH/WILDLIFE

OTHER

STATES

RESPONSE CODE 38

RESPONSE DATE

MAY 10 2000 ✓

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAY 10 2000

ETI H2O, Inc.
Route 14, Box 1517
Lake City, FL 32054

Attn.: John Kennedy, Agent

Subject: AXEN
EPA File Symbol 72977-E
Application Dated November 28, 1999

The application referred to above submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act as amended is incomplete. Before the agency can continue processing your application you must satisfy the deficiencies listed below.

1. Refer to the attached Product Chemistry Science Review for data deficiencies. Corrections and clarifications must be made on the Confidential Statement of Formula form, and in the declaration of the appropriate active ingredient. As discussed by phone with the company representative, silver citrate may be a new chemical, but a final determination will be held in abeyance until the agency has met with the company to discuss the chemistry of the product.
2. Refer to the attached Product Toxicity Science Review for data deficiencies. The submitted primary eye irritation study is acceptable ; however, the application package make no mention of the other acute

CONCURRENCES

| | | | | | | | | |
|-------|--|--|--|--|--|--|--|--|
| MBOL | | | | | | | | |
| RNAME | | | | | | | | |
| TE | | | | | | | | |

toxicity data requirements. Data support for each must be submitted. As discussed by phone with the company representative, additional toxicity data, environmental fate, ecological effects, efficacy, and exposure data will also be required if the active ingredient is determined to be a new pesticide active ingredient.

The agency reserves a full label review until after the above deficiencies have been satisfied.

If you have any questions concerning this letter please contact Marshall Swindell at 703-308-6341.

Sincerely yours,

Marshall Swindell
Product Manager 33
Regulatory Management Branch 1
Antimicrobials Division (7510C)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

05/08/00

MEMORANDUM

Subject: D263138
AXEN[®], EPA File Symbol 72977-E

From: Wallace Powell, Biologist *Wallace Powell*
Product Science Branch
Antimicrobials Division (7510C) 5-8-00

Thru: Karen P. Hicks, Team Leader
Chemistry/Toxicology Team
Product Science Branch
Antimicrobials Division (7510C) *K. Hicks*
5/9/00

Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

To: Marshall Swindell, Product Manager, Team 33
Regulatory Management Branch I
Antimicrobials Division (7510C)

BACKGROUND

In an application for registration of AXEN[®], EPA File Symbol 72977-E, the applicant, ETI H2O, Inc. (as represented by an agent), has submitted a primary eye irritation study, MRID 450165-01. The product label is labeled as a hard surface disinfectant spray containing the active ingredients Axenohl[®] (0.0012% of the formulation by weight) and [REDACTED]

RECOMMENDATION

The submitted primary eye irritation study, MRID 450165-01, is acceptable and places AXEN in acute toxicity Category IV for eye irritation.

The application package makes no mention of the other acute toxicity data requirements – acute oral toxicity, acute dermal toxicity, acute inhalation toxicity, primary dermal irritation, and dermal sensitization. Data support for each must be

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submitted. Data support can be direct (submitted studies, which is generally the recommended approach) or indirect (cited or submitted studies, or waiver requests with specific rationales).

Based on the final component entry in the Confidential Statement of Formula (CSF) dated 11/28/99, it appears as if Axenohl® is the product, which contains [REDACTED]. However, the label implies that Axenohl® is merely a component of the product. (The reviewer assumes that that CSF entry refers to a process whereas the rest of the CSF represents the final product.) PSB will need clarification on this matter if acute toxicity data waivers are requested, or if studies are cited which were conducted on other products.

PRODUCT LABELING

Determination of the required precautionary (human hazard) and first-aid (practical treatment) label statements cannot be completed until the acute toxicity data requirements have all been met.

AXENOHLE® (1,1-DIMETHYL-2-PYRROLIDINE) 100% PURE

214

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING

Reviewer: W. Powell
Product No.: 72977-E
DP Barcode: D263138
MRID No.: 450165-01
Report No.: 8115 (Study No.)
Study Completion: 10/06/99
Author: George E. Moore

Conclusion:
Toxicity Category: IV
Classification: Acceptable
Quality Assurance (40 CFR §160.12): Included
Procedure Deviations: None noted

Testing Facility: Product Safety Labs
725 Cranbury Road, East Brunswick, NJ 08816

Test Material: AXEN, Lot #8995A, a clear liquid

Test Animal:
Rabbit, New Zealand albino
Age: Adult
Weight: Not indicated
Source: Davidson's Mill Farm, South Brunswick, NJ

Test Method:

0.1 mL of the undiluted test material was instilled into the conjunctival sac of one eye of each of three rabbits (1 female, 2 males) that were pre-screened for health and for eye abnormalities. Upon instillation, eyelids of the treated eyes were held together for approximately 1 second. The untreated eye served as a control. Ocular irritation was evaluated and graded according to the Draize criteria, at 1, 24, 48, and 72 hours post-instillation. Fluorescein solution was employed at 24 hours to verify absence of corneal opacity.

Results and Discussion:

No 'positive' conjunctival irritation, corneal opacity, or iridal involvement was observed during the study. Irritation was limited to conjunctival redness of grade 1 (i.e., vessels injected above normal) in 2/3 animals at 1 hour post-instillation. This cleared by the 24 hour observation. All animals appeared active and healthy. The data place the test material in acute Toxicity Category IV for eye irritation.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

SUBJECT: Product Chemistry Review of Axen

DP Barcode: **D263136**

Reg. No. or File Symbol: **72977-E**

Manufacturing-use []

End-use Product [X]

Active Ingredient Composition:

*Axenohl.....0.0012%

*Silver citrate generated electrically

TO: Marshall Swindell PM 33

FROM: Alex Traska, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510C)

At 3/31/00

THRU: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510C)

*Karen P. Hicks
4/3/00*

THRU: Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510 C)

BACKGROUND:

This application for a new product registration, for the subject disinfectant spray, was submitted by John W. Kennedy Consultants, Inc. on behalf of the registrant, ETI H2O, Inc.

216

In support of the new registration for **Axen** a hard surface disinfectant spray, the following documents were submitted and examined in the chemistry review of this submission: agent's cover letter (date missing), Basic Formulation CSF dated 11/28/99, product label dated 1/11/00, Product Chemistry Data-Guidelines 61, 62 and 63. Also examined for this review was pending jacket file #72977-E.

FINDINGS:

1. The following deficiencies were noted in the review of the CSF:

- a. Item 1 and 2 of the CSF were incomplete
- b. provide source of supply for all components utilized in the formulation as required in item 11
- c. CAS Reg. Nos. should be provided for all components used in the formula as required in item 10
- d. the CAS Reg. No. for citric acid is 77-92-9 and not 126-45-4 as given in the CSF

2. [REDACTED] is a dispersant and an inert ingredient as given in the CSF. [REDACTED] should, therefore, not be listed in the ingredient statement as an active ingredient.

3. The use of 4.8% citric acid in the formulation as a dispersant for silver citrate is questioned since silver citrate is only present at a 0.0012% level.

It appears that the primary effect of citric acid in the formulation is that of an active ingredient. At a 4.8% level citric acid should be treated as an active ingredient since at this level it provides significant germicidal properties to the formulation.

4. The registered trade mark "Axenohl" cannot be used in the active ingredient declaration. The common chemical name must be used in the declaration of ingredients e.g. silver citrate.

Based on the prior comments, the requirements of PR Notice 91-2 have not been satisfied.

5. The active ingredient, silver citrate, is not for use in pesticide formulations. A MSDS including a complete chemical characterization of the active ingredient must be provided to initiate the clearance of silver citrate by the Agency.

6. The following deficiencies were noted in the review of the Product Chemistry Data package:

- a. test parameters for pH were not provided e.g. percent concentration of test solution, temperature
- b. no initial 30 day storage stability study was provided and the one-year study is still outstanding
- c. it is not clear from the discussion of the manufacturing process whether the disinfectant spray is a propellant driven aerosol spray or a pump spray

RECOMMENDATIONS:

This application, for the new product registration of **Axen**, is not accepted. Deficiencies noted under Findings must be corrected and all additional information requested must be provided for further Agency review.

3/31/00 AT



JOHN W. KENNEDY CONSULTANTS, INC.

13 "C" Street, Suite G, Laurel, MD 20707
Telephone: (301) 480-8500, FAX: (301) 480-8750

480165-00

Marshall Swindell
Product Manager 33
Antimicrobial Biogram Division (H7505)
U.S. Environmental Protection Agency
Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA. 22202

Subject: New Registration For AXEN
Company Number 72977-E

Dear Marshall,

John W. Kennedy Consultants represents ETI H2O in all matters dealing with pesticide and Food and Drug clearances.

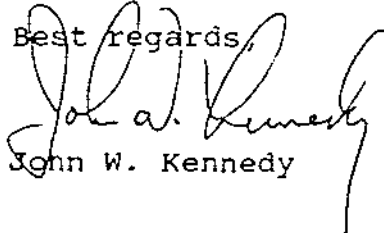
Support for the subject product is attached to the application for AXEMOHL (technical) except chemistry and one toxicology study (Primary Eye Irritation in Rabbit).

The following data are attached to this submission:

- (1) Application for Pesticide
- (2) Certification with Respect to Citation of Data
- (3) Confidential Statement of Formula
- (4) Proposed Label
- (5) Data Matrix
- (6) Data Submissions

Please note that ETI H2O is going the Selective Method.

Best regards,


John W. Kennedy

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

ETI H2O

Tre 14, Box 1517

Lake City, FL 32054

REGULATORY ACTION:

New Application - Axen page 1

TRANSMITTAL DATE:

11-28-99

LIST OF SUBMITTED STUDIES:

45016501

Mrid No.

VOLUME 1 - Primary Eye Irritation Study
in Rabbits

45016502

Mrid No.

VOLUME 2 - Product Identity and Composition - Axen

VOLUME 3 -

Mrid No.

VOLUME 4 -

Mrid No.

VOLUME 5 -

Mrid No.

COMPANY OFFICIAL:

John W. Kennedy
TYPED NAME

John W. Kennedy
SIGNATURE

COMPANY NAME:

ETI H2O

(Consultant)

COMPANY CONTACT:

John W. Kennedy
TYPED NAME

(301) 490-1600
TELEPHONE

Kennedy Consultants

13th St., Suite G

Laurel, MD 20707

Page ____ is not included in this copy.

Pages 221 through 222 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
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- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
- ☐ The document is not responsive to the request.

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JAN 27 2000

U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs

ETI H20
RT. 14, BOX 1517
LAKE CITY, FL 32054

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 01/11/00. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



JOHN W. KENNEDY CONSULTANTS, INC.

13 "C" STREET, SUITE G, LAUREL, MD 20707
TELEPHONE: (301) 490-1800, FAX: (301) 490-5793

460165-00

Marshall Swindell
Product Manager 33
Antimicrobial Biogram Division (H7505)
U.S. Environmental Protection Agency
Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA. 22202

Subject: New Registration For AXEN
Company Number 72977-*E*

Dear Marshall,

John W. Kennedy Consultants represents ETI H2O in all matters dealing with pesticide and Food and Drug clearances.

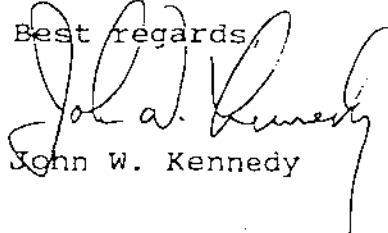
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The following data are attached to this submission:

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- (6) Data Submissions

Please note that ETI H2O is going the Selective Method.

Best regards,


John W. Kennedy

TRANSMITTAL DOCUMENT

NAME AND ADDRESS OF SUBMITTER:

ETI H2O

Tre 14, Box 1517

Lake City, FL 32054

REGULATORY ACTION: New Application - Axen page 1

TRANSMITTAL DATE: 11-28-99

LIST OF SUBMITTED STUDIES:

45016501

Mrid No.

VOLUME 1 - Primary Eye Irritation Study
in Rabbits

45016502

Mrid No.

VOLUME 2 - Product Identity and Composition - Axen

Mrid No.

VOLUME 3 -

Mrid No.

VOLUME 4 -

Mrid No.

VOLUME 5 -

COMPANY OFFICIAL:

John W. Kennedy
TYPED NAME

John W. Kennedy
SIGNATURE

COMPANY NAME:

ETI H2O

(Consultant)

COMPANY CONTACT:

John W. Kennedy
TYPED NAME

(301) 490-1600
TELEPHONE

Kennedy Consultants

13 "C" St., Suite G

Laurel, MD 20707

Page ____ is not included in this copy.

Pages 226 through 229 are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
- ☒ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
- ☐ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

FQPA

DP BARCODE: D263136

CASE: 068118
SUBMISSION: S574918

DATA PACKAGE RECORD
BEAN SHEET

DATE: 02/10/00
Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REGISTRATION ACTION: 188 FQPA-OC-ME TOO ADDL USE
CHEMICALS: [REDACTED]

0.0010%

ID#: 072977-E AXEN

COMPANY: 072977 ETI H2O, INC.

PRODUCT MANAGER: 33 MARSHALL SWINDELL

703-308-6341

ROOM: CS1

6B

PM TEAM REVIEWER: PAMELA HASTY

703-308-7933

ROOM: CS1

6W15

RECEIVED DATE: 01/11/00

DUE OUT DATE: 05/10/00

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 263136

EXPEDITE: N

DATE SENT: 02/10/00

DATE RET.: / /

CHEMICAL: [REDACTED]

TP TYPE: 001

CSF: Y

LABEL: Y

ASSIGNED TO

DATE IN

DATE OUT

ADMIN DUE DATE: 05/15/00

DIV : AD

/ /

/ /

NEGOT DATE: / /

BRAN: PSB

/ /

/ /

PROJ DATE: / /

SECT: CTT

/ /

/ /

REVR :

/ /

/ /

CONTR:

/ /

/ /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the chemistry data for acceptability.

* * * DATA PACKAGE EVALUATION * * *

No evaluation is written for this data package

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

| DP BC | BRANCH/SECTION | DATE OUT | DUE BACK | INS | CSF | LABEL |
|--------|----------------|----------|----------|-----|-----|-------|
| 263138 | PSB/CTT | 02/10/00 | 05/15/00 | Y | Y | Y |

NOTE: NO CHEMIST INFORMATION IS NOT INCLUDED

230

Page 23 is not included in this copy.

Pages ____ through ____ are not included in this copy.

The material not included contains the following type of information:

- ☐ Identity of product inert ingredients.
- ☐ Identity of product impurities.
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- ☐ Description of quality control procedures.
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- ☐ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☒ The document is a duplicate of page(s) 230.
- ☐ The document is not responsive to the request.

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DATE 1/13/00

FILE NUMBER 72977-E

 No Data - File Room "Make Ready for "
(FM or Individual)

✓ Data - File Room "Assign Jacket to Shelf"

 Rejected - File Room "Assign Jacket to Rejected Shelf"

FRONT END PROCESSING APPLICATION INFORMATION CHECK

DATE: 1/13/00

PM 33

EPA COMPANY NUMBER 72977-E

EPA REGISTRATION NUMBER
STATUS (For Amendments)

Active _____ Cancelled _____

Not in REFS _____

"Me-Too" CITED PRODUCT STATUS

Active _____ Cancelled _____

Not in REFS _____

PRAT RECORD CREATED ^{Yes} 1/13/00

NIFT

Read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0050. Approval expires 2-28-95



United States
Environmental Protection Agency
Washington, DC 20460

☒ Registration
☐ Amendment
☐ Other

PPP Identifier Number

256680
230031

Application for Pesticide - Section I

| | | |
|---|--|--|
| Company/Product Number
ETI H20 72977-E | 2. EPA Product Manager
Margaret Swindell ✓ | 3. Proposed Classification
<input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| Company/Product (Name)
Axen | PMF
Team 33 ✓ | |
| Name and Address of Applicant (Include ZIP Code)
ETI H20
Route 14, Box 1517
Lake City, FL 32054
<input type="checkbox"/> Check if this is a new address | 5. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:
EPA Reg. No. _____
Product Name _____ | |

Section - II

| | |
|--|--|
| <input type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Submission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input checked="" type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

New registration

Section - III

Material This Product Will Be Packaged In:

| | | | |
|--|--|---|---|
| 1. d-Resistant Packaging
<input type="checkbox"/> Yes
<input checked="" type="checkbox"/> No | Unit Packaging
<input checked="" type="checkbox"/> Yes
<input type="checkbox"/> No | Water Soluble Packaging
<input type="checkbox"/> Yes
<input checked="" type="checkbox"/> No | 2. Type of Container
<input checked="" type="checkbox"/> Metal
<input type="checkbox"/> Plastic
<input type="checkbox"/> Glass
<input type="checkbox"/> Paper
<input type="checkbox"/> Other (Specify) _____ |
| 3. If "Yes" Unit Packaging wgt. 24 oz. No. per container 12 | | 4. If "Yes" Package wgt. _____ No. per container _____ | |
| Location of Net Contents Information
<input type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container
2 oz. to 55 gallons | 5. Location of Label Directions
<input checked="" type="checkbox"/> On Label
<input checked="" type="checkbox"/> On Labeling accompanying product |
| Manner in Which Label is Affixed to Product
<input checked="" type="checkbox"/> Lithograph
<input type="checkbox"/> Paper glued
<input type="checkbox"/> Stenciled <input type="checkbox"/> Other _____ | | | |

Section - IV

Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

| | | |
|---|--|---|
| Name
John W. Kennedy | Title
President of Kennedy Consultants - Consultant to ETI H20 | Telephone No. (Include Area Code)
301-490-1600 |
| Certification
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | 6. Date Application Received (Stamped) |
| Signature
John W. Kennedy | 3. Title
President of John W. Kennedy Consultants - Consultant to ETI H20 | 5. Date
12/28/99 |
| Printed Name
John W. Kennedy | | |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

01/13/2000

OFFICE OF
PREVENTION, PESTICIDE AND
TOXIC SUBSTANCES

ETI H20
Route 14, Box 1517
Lake City, FL 32054

PRODUCT NAME: Axen
COMPANY NAME: ETI H20
OPP IDENTIFICATION NUMBER: 256680
EPA FILE SYMBOL: 72977-E
EPA RECEIPT DATE: 01/11/2000

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The Office of Pesticides Programs has received your application for a new registration and it has passed an administrative screen for completeness.

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval.

If you have any questions please contact Marshall Swindell, Product Manager 33, at (703)-308-6341.

Sincerely,

A handwritten signature in cursive script, appearing to read "Annie L. Horn".

Front End Processing Staff
Information Services Branch
Information Resources & Services Division

N/FT



JOHN W. KENNEDY CONSULTANTS, INC.

13 "C" STREET, SUITE G, LAUREL, MD 20707
TELEPHONE: (301) 490-1600, FAX: (301) 490-5793

Marshall Swindell
Product Manager 33
Antimicrobial Biogram Division (H7505)
U.S. Environmental Protection Agency
Crystal Mall 2
1921 Jefferson Davis Highway
Arlington, VA. 22202

Subject: New Registration For AXEN
Company Number 72977-E

Dear Marshall,

John W. Kennedy Consultants represents ETI H2O in all matters dealing with pesticide and Food and Drug clearances.

Support for the subject product is attached to the application for AXEMOHL (technical) except chemistry and one toxicology study (Primary Eye Irritation in Rabbit).

The following data are attached to this submission:

- (1) Application for Pesticide
- (2) Certification with Respect to Citation of Data
- (3) Confidential Statement of Formula
- (4) Proposed Label
- (5) Data Matrix
- (6) Data Submissions

Please note that ETI H2O is going the Selective Method.

Best regards,

John W. Kennedy
John W. Kennedy

5 4 3 2 1



JOHN W. KENNEDY CONSULTANTS, INC.

13 "C" STREET, SUITE G, LAUREL, MD 20707
TELEPHONE: (301) 450-1600, FAX: (301) 450-5793

Mr. Marshall Swindell
Product Manager 33
Antimicrobial Biogram Branch
Registration Division (H7505C)
Environmental Protection Agency
Crystal Mall No. 2
1921 Jefferson Davis Highway
Arlington, VA. 22202

Subject: New Registration For AXEN and AXENOHL
Company number 72977

Dear Marshall,

AXEN is a end-use product formulated by the dilution of AXENOHL (technical product).

Axenohl® is a combination of electrolytically generated silver, citric acid and [REDACTED]

Registration is being sought from EPA for use as a hard surface disinfectant. Many organisms are controlled at dilute (<12 ppm Ag⁺ or less) including *Salmonella choleraesuis*, *Pseudomonas aeruginosa*, *Staphylococcus aureus*, and *Enterococcus faecium*. *Enterococcus faecium* was tested as a surrogate for drug resistant (i.e. Vancomycin Resistant *Enterococcus*, (VRE)) bacteria.

Axenohl® is not a colloidal preparation of silver, but is an organic acid/silver complex. Without the organic acid, silver is neither as effective nor as stable. The acid maintains stability and solubility.

Toxicity studies have been done in conjunction with the EPA submission. The results are as follows for Axenohl®, the technical concentrate (ca. 2,400 ppm Ag⁺):

- | | |
|--------------------------|--|
| 1. Acute Oral Toxicity | LD ₅₀ > 5,000 mg/Kg |
| 2. Acute Dermal Toxicity | LD ₅₀ > 5,000 mg/Kg |
| 3. Dermal Sensitization | Not a contact sensitizer |
| 4. Ocular Irritation | Mildly irritating. Irritation cleared by 72 hours. Category 3. |
| 5. Dermal Irritation | Slightly irritating at 72 hours. |

For the diluted product, Axen®, at proposed use level concentrations (ca. 12 ppm Ag⁺):

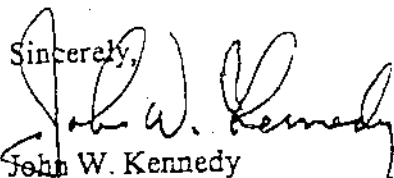
- | | |
|----------------------|---|
| 1. Ocular Irritation | Practically non-irritating. Irritation cleared by 24 hours. Category 4. |
|----------------------|---|

These results indicate that Axenohl® and Axen® are non-toxic and can even be used in the eye with little problem. Neutralization for eye uses would likely reduce the irritation even more.

Silver and silver compounds control over 650 different microbes, i.e. bacteria and fungi as cited

237

by the National Academy of Sciences.

Sincerely,


John W. Kennedy
John W. Kennedy Consultants, Inc.
Agent for ETI H2O



Disinfection With Environmental Perspective

ETI H2O, Inc.
Rt. 14 Box 1517, Lake City, FL 32024
V. 904-755-0389 FAX: 904-755-8642
E-Mail: microbio@alltel.net

Date: 10-18-99

To Whom it may concern:

ETI H2O, Inc. authorizes John W. Kennedy Consultants, Inc. of 13 "C" Street, Suite G, Laurel, MD 20707 to act on behalf of ETI H2O, Inc. on all matters relating to regulatory actions before the US Environmental Protection Agency, the Food and Drug Administration and the State Regulatory Authorities.

Sincerely:

A handwritten signature in black ink, appearing to read "Andrew B. Arata". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Andrew B. Arata
President and CEO

Cc: Dr. Edwin Woolson, EPL-BAS



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

| | | |
|---|--|---|
| Applicant's/Registrant's Name, Address, and Telephone Number
<u>ETI H2O, Route 14, Box 1517, Lake City, FL</u> | Consultant (John Kennedy)
<u>(800) 490-1600</u> | EPA Registration Number/File Symbol
<u>72977-E</u> |
| Active Ingredient(s) and/or representative test compound(s)
<u>Silver Citrate</u> | Date
<u>11/28/99</u> | |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)
<u>Guideline 91-2 Surface disinfectants</u> | Product Name
<u>AXEN</u> | |

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

SECTION II: GENERAL OFFER TO PAY

Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is selected in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| | | |
|-------------------------------------|-------------------------|--|
| Signature
<u>John W. Kennedy</u> | Date
<u>11/28/99</u> | Typed or Printed Name and Title
<u>John W. Kennedy - Consultant</u> |
|-------------------------------------|-------------------------|--|



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

| Date <u>Nov. 23, 1999</u> | | EPA Reg No./File Symbol <u>72977-E</u> | | Page <u>1</u> of <u>1</u> | |
|--|--|--|---|---------------------------|----------------------|
| Applicant's/Registrant's Name & Address
<u>ETI H2O</u>
<u>Tre 14, Box 1517</u>
<u>Lake City, FL 32054</u> | | Product
<u>Axen</u> | | | |
| Ingredient <u>Silver</u> | | | | | |
| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
| <u>331512 870.1100</u> | <u>Acute Oral Tox in rats - Limit Test</u> | | <u>ETI H2O</u> | <u>own</u> | <u>#1</u> |
| <u>331506 870.1200</u> | <u>Acute Dermal Tox in rats - Limit Test</u> | | <u>" "</u> | <u>own</u> | <u>#1</u> |
| <u>331507 870.2400</u> | <u>Primary Eye Irritation in Rabbits</u> | | <u>" "</u> | <u>own</u> | <u>#1</u> |
| <u>331508 870.2500</u> | <u>Primary Skin Irritation in Rabbits</u> | | <u>" "</u> | <u>own</u> | <u>#1</u> |
| <u>331509 870.2600</u> | <u>Dermal Sensitization in Guinea Pig</u> | | <u>" "</u> | <u>own</u> | <u>#1</u> |
| <u>331516 870.2400</u> | <u>Primary Eye Irritation in Rabbits</u> | | <u>" "</u> | <u>own</u> | |
| <u>Series 61, 62, 63</u> | <u>Product Chemistry</u> | | <u>" "</u> | <u>own</u> | |
| <u>91-2</u> | <u>Efficacy - Key</u> | | <u>" "</u> | <u>own</u> | <u>#2</u> |
| <u>91-2</u> | <u>Efficacy - Microbiotest</u> | | <u>" "</u> | <u>own</u> | <u>#2</u> |
| Footnote #1 - <u>Studies done on concentrate product: Axenoh!</u> | | | | | |
| Footnote #2 - <u>Study Reference from concentrate product Axenoh!</u> | | | | | |
| Signature <u>[Signature]</u> | | | Name and Title <u>Consultant to</u>
<u>ETI-H2O</u> | | Date <u>11/28/99</u> |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB

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DATA MATRIX

Date Nov. 28, 1999

EPA Reg No./File Symbol 72977-E

Page 1 of 1

Applicant's/Registrant's Name & Address ETI H2O
Tre 14, Box 1517
Lake City, FL 32054

Product Axen

Ingredient Silver

Guideline Reference Number

Guideline Study Name

MRID Number

Submitter

Status

Note

ETI H2O

own

#1

" "

own

#1

" "

own

#1

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own

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own

#1

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own

#2

" "

own

#2

Site: Axenoh!

Product Axenoh!

Signature

John W. Kennedy

Name and Title Consultant to
ETI-H2O

Date

11/28/99

Page ____ is not included in this copy.

Pages 243 through 244 are not included in this copy.

The material not included contains the following type of information:

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- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
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- ☒ A draft product label.
- ☐ The product confidential statement of formula.
- ☐ Information about a pending registration action.
- ☐ FIFRA registration data.
- ☐ The document is a duplicate of page(s) _____.
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FOR OFFICIAL USE ONLY

FILE SYMBOL

E

REGISTRATION NO.

72977

CONFIDENTIAL STATEMENT OF FORMULA ENCLOSED

| DATE
SUBMITTED | SUBMITTED BY (/) | |
|-----------------------------------|------------------|----------------|
| | APPLICANT | BASIC SUPPLIER |
| <i>1/13/00</i>
<i>12/28/99</i> | | |
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**Do Not Write Comments,
Formula, or Parts of Formula
on This Envelope**

NOTE

It shall be unlawful--for any person to use for the person's own advantage or to reveal, other than to the Administrator, or officials or employees of the Environmental Protection Agency or other Federal executive agencies, or to the courts, or to physicians, pharmacists, and other qualified persons, needing such information for the performance of their duties, in accordance with such directions as the Administrator may prescribe, any information acquired by authority of the "Federal Insecticide, Fungicide, and Rodenticide Act" which is confidential under this Act.

Page ____ is not included in this copy.

Pages 246 through 259 are not included in this copy.

The material not included contains the following type of information:

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- ☐ Identity of product impurities.
- ☐ Description of the product manufacturing process.
- ☐ Description of quality control procedures.
- ☐ Identity of the source of product ingredients.
- ☐ Sales or other commercial/financial information.
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